UNITED STATE DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Case No.: l:18-cv-04814-AJN

JODI ROUVIERE, Individually and
ANDRE ROUVIERE, her husband, Individually,

Plaintiff

v.

DEPUY ORTHOPAEDICS, INC.,
DEPUY PRODUCTS, INC.,
DEPUY INTERNATIONAL, LIMITED,
JOHNSON & JOHNSON, INC.,
and JOHNSON & JOHNSON SERVICES, INC.,
and STRYKER CORPORATION,
STRYKER SALES CORPORATION, and
HOWMEDICA OSTEONICS CORPORATION,
d/b/a STRYKER ORTHOPAEDICS

Defendants
_____/

DEPUY DEFENDANTS' ANSWER TO PLAINTIFFS' AMENDED COMPLAINT FOR DAMAGES

Defendants DePuy Orthopaedics, Inc. n/k/a Medical Device Business Services, Inc., DePuy Products, Inc. (collectively "DePuy Defendants"), DePuy International Limited, Johnson & Johnson and Johnson & Johnson Services, Inc. for their answer to Plaintiffs' Amended Complaint for Damages state as follows:

I. INTRODUCTION

1. As detailed below, Plaintiffs brings this action for damages for severe and permanent personal injuries including elevated blood levels of chromium, chromium toxicity, elevated blood levels of cobalt, cobalt toxicity, titanium, titanium toxicity, inflammation, pain, swelling, loss of range of motion, surgical removal and revision of

hip replacement system, hip explant, pain and suffering, economic loss, and permanent disability, all of which Jodi Rouviere has sustained as a consequence of being implanted with the defendants Depuy' "Summit" total hip arthroplasty system stem (" Summit Tapered Hip System Stem") and defendant Stryker MDM®X3®" ADM/MDM System, "The Restoration".

ANSWER: DePuy Defendants deny the allegations in paragraph 1 to the extent they are directed against the DePuy Defendants. DePuy Defendants explicitly deny that its product or products were defective or injured Plaintiffs. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 1.

2. The Summit Tapered Hip System is a hip replacement system designed, developed, tested, manufactured, assembled, packaged, promoted, labeled, marketed, distributed and sold by the defendants DEPUY ORTHOPAEDICS, INC., DEPUY PRODUCTS, INC., DEPUY INTERNATIONAL, LIMITED, JOHNSON & JOHNSON, INC., and JOHNSON & JOHNSON SERVICES, INC.

ANSWER: DePuy Defendants admit that DePuy Orthopaedics, Inc., n/k/a Medical Device Business Services, Inc. was in the business of designing, developing, testing, manufacturing, assembling, packaging, distributing and selling the Summit Tapered Hip System. DePuy Defendants lack knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 2.

3. Numerous adverse event reports regarding the widespread failures of the Summit Tapered Hip System Stem have been filed with the FDA. The Summit Tapered Hip System including stem, has injured many people, including Mrs. Rouviere. Moreover,

defendants continue to market the Summit Tapered Hip System and stem with the same design as the Summit Tapered Hip System stem implanted in Mrs. Rouviere.

ANSWER: DePuy Defendants deny the Summit Tapered Stem Hip System has caused injury and lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 3.

4. The Summit Tapered Hip System Stem implanted in, and consequently explanted, from Mrs. Rouviere will hereinafter be referred to as the "Depuy subject product."

ANSWER: DePuy Defendants make no response to rhetorical paragraph 4, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 4.

5. The venue for this action lies in the Southern District of New York.

ANSWER: Paragraph 5 contains legal statements or conclusions to which no response is required.

6. The Depuy subject product Summit stem was implanted at The Hospital of Special Surgery, in New York County and within the Southern District of New York, on August 17, 2012. Plaintiff underwent revision surgery to repair the faulty implant and discovered extreme metallosis in the tissue surrounding the implant on November 11, 2016 at Baptist Hospital Miami Florida. Before and after the revision, the plaintiff experienced elevated metal levels and instability, on February 17, 2017, Mrs. Rouviere had the Depuy Summit Stem removed.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6.

7. "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System is a hip replacement system designed, developed, tested, manufactured, assembled, packaged, promoted, labeled, marketed, distributed and sold by the defendants STRYKER CORPORATION, STRYKER SALES CORPORATION, and HOWMEDICA OSTEONICS CORPORATION, d/b/a STRYKER ORTHOPAEDICS.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations pertaining to the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System against the DePuy Defendants. DePuy Defendants deny the allegations in paragraph 7 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 7.

8. Numerous adverse event reports regarding the widespread failures of "MDM X3" ADM/MDM System, "The Restoration®" ADM/MDM System have been filed with the FDA. The MDM®X3®" ADM/MDM System has injured many people, including Mrs. Rouviere. Moreover, defendants continue to market MDM X3" ADM/MDM System, "The Restoration®" ADM/MDM System with the same design as the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System implanted in Mrs. Rouviere.

ANSWER: DePuy Defendants deny the allegations in paragraph 8 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 8.

9. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System implanted in, and consequently explanted, from Mrs. Rouviere will hereinafter be referred to as the "Stryker subject product."

ANSWER: DePuy Defendants make no response to rhetorical paragraph 9, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 9.

10. The venue for this action lies in the Southern District of New York.

ANSWER: Paragraph 10 contains legal statements or conclusions to which no response is required.

11. The Stryker subject product was implanted at The Hospital of Special Surgery, in New York County and within the Southern District of New York, on August 17, 2012. Plaintiff underwent revision surgery to repair the faulty implant and discovered extreme metallosis in the tissue surrounding the implant on November 11, 2016 at Baptist Hospital Miami Florida. Before and after the revision, the plaintiff experienced elevated metal levels and instability, on February 17, 2017, Mrs. Rouviere had the Stryker acetabular cup removed.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11.

12. Venue is appropriate in the Southern District of New York pursuant to 28 U.S.C. §1391(b)(2).

ANSWER: Paragraph 12 contains legal statements or conclusions to which no response is required.

II. THE PARTIES

13. Plaintiff Jodi Rouviere is a resident of Miami Florida.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13.

14. Plaintiff Andre Rouviere is a resident of Miami Florida.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14.

15. Plaintiff Jodi Rouviere is domiciled in the State of Florida.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 15.

16. Plaintiff Andre Rouviere is domiciled in the State of Florida, and at all times, the legal husband of the plaintiff Jodi Rouviere.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16.

17. Plaintiff Jodi Rouviere is a citizen of the State of Florida.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17.

18. Plaintiff Andre Rouviere is a citizen of the State of Florida.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18.

19. Defendant DEPUY ORTHOPAEDICS, INC ("DEPUY ORTHOPEDICS") is a corporation existing under the laws of the state of Indiana with its principal place of business in Warsaw, Indiana, 700 Orthopaedic Drive, Warsaw, Indiana 46581.

ANSWER: DePuy Defendants admits that DePuy Orthopaedics, Inc. n/k/a Medical Device Business Services, Inc. is an Indiana corporation with its principal place of business located in Warsaw, Indiana.

20. Defendant DEPUY ORTHOPEDICS designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System that is the subject of this lawsuit, and does business in the Southern District of New York.

ANSWER: DePuy Defendants admits that DePuy Orthopaedics, Inc. n/k/a Medical Device Business Services, Inc. designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System.

21. Defendant DEPUY PRODUCTS, INC ("DEPUY PRODUCTS") is a corporation existing under the laws of the state of Indiana with its principal place of business in Warsaw, Indiana, 700 Orthopaedic Drive, Warsaw, Indiana 46581.

ANSWER: DePuy Defendants admit that DePuy Products, Inc. is an Indiana corporation with its principal place of business located in Warsaw, Indiana.

22. Defendant DEPUY PRODUCTS designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System that is the subject of this lawsuit, and does business in the Southern District of New York.

ANSWER: DePuy Defendants denies the allegations contained in Paragraph 22 as to DePuy Products.

23. Defendant, DEPUY INTERNATIONAL, LIMITED ("DEPUY INTERNATIONAL") is a subsidiary of DEPUY ORTHOPAEDICS. DEPUY INTERNATIONAL is a private limited company, as that term is defined by the laws of the United Kingdom, having a principal place of business in Leeds, West Yorkshire, United Kingdom (St. Anthony's Road, Beeston, UK LSI 1 8DT).

ANSWER: DePuy Defendants admit that DePuy International Limited is a limited liability company organized and existing pursuant to the laws of the United Kingdom, with its principal place of business in the United. Kingdom. DePuy Defendants deny all remaining allegations in Paragraph 23.

24. Defendant DEPUY INTERNATIONAL designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System that is the subject of this lawsuit, and does business in the Southern District of New York.

ANSWER: DePuy Defendants denies the allegations contained in Paragraph 24 as to DePuy International Limited and deny that this Court has personal jurisdiction over DePuy International Limited.

25. Defendant JOHNSON & JOHNSON, INC. ("J&J") is a corporation existing under the laws of the state of New Jersey with its principal place of business located at One Johnson and Johnson Plaza. New Brunswick, New Jersey 08933.

ANSWER: DePuy Defendants admit that Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

26. Defendant J&J is the parent company of DEPUY ORTHOPAEDICS.

ANSWER: DePuy Defendants admit that Johnson & Johnson is the parent company of DePuy Orthopaedics n/k/a Medical Device Business Services, Inc.

27. Defendant J&J, as parent to defendant DEPUY ORTHOPAEDICS, designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System that is the subject of this lawsuit, and does business in the Southern District of New York.

ANSWER: DePuy Defendants deny the allegations contained in Paragraph 27 at to Johnson & Johnson and deny that this Court has personal jurisdiction over Johnson & Johnson.

28. Defendant JOHNSON & JOHNSON, SERVICES INC. ("J&J SERVICES") is a corporation existing under the laws of the state of New Jersey with its principal place of business located at One Johnson and Johnson Plaza, New Brunswick, New Jersey 08933.

ANSWER: DePuy Defendants admit Johnson & Johnson Services, Inc. is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

29. Defendant J&J SERVICES is the parent company of DEPUY ORTHOPAEDICS.

ANSWER: DePuy Defendants deny the allegations contained in Paragraph 29.

30. Defendant J&J SERVICES, as parent to defendant DEPUY ORTHOPAEDICS, designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System that is the subject of this lawsuit, and does business in the Southern District of New York.

ANSWER: DePuy Defendants deny the allegations contained in Paragraph 30 as to Johnson & Johnson Services, Inc. and deny that this Court has personal jurisdiction over Johnson & Johnson Services, Inc.

31. Defendants DEPUY ORTHOPAEDICS, DEPUY PRODUCTS, DEPUY INTERNATIONAL, J&J, and J&J SERVICES are referred to collectively as "Defendants."

ANSWER: DePuy Defendants make no response to rhetorical paragraph 31, as it is purely explanatory in nature. DePuy Defendants deny that this Court has personal jurisdiction over Defendants DePuy International Limited, Johnson & Johnson and Johnson & Johnson Services, Inc. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 31.

32. Each of the Defendants is a business engaged in designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, advertising, marketing, distributing, and selling medical devices, including the Summit Tapered Hip System, including the stem.

ANSWER: DePuy Defendants admit that DePuy Orthopaedics n/k/a Medical Device Business Services, Inc. was in the business of designing, developing, testing, manufacturing, assembling, packaging, distributing and selling the Summit Tapered Hip System. DePuy Defendants deny the remaining allegations in Paragraph 32 and deny that this Court has personal jurisdiction over DePuy International Limited, Johnson & Johnson and Johnson & Johnson Services, Inc.

33. At all times mentioned, each of the Defendants was the representative, agent, employee, joint venture participant, or alter ego of each of the other entities and in doing the things alleged herein was acting within the scope of its authority as such. Specifically, each defendant was an instrumentality or conduit of the other in the pursuit of the design, promotion, and sale of the Summit Tapered Hip System.

ANSWER: DePuy Defendants deny the allegations contained in Paragraph 33. DePuy Defendants deny that this Court has personal jurisdiction over Defendants DePuy International Limited, Johnson & Johnson and Johnson & Johnson Services, Inc.

34. Each of the Defendants transacts business in New York State, including in New York County within the Southern District of New York, where Plaintiff received the subject product, the Summit Tapered Hip System.

ANSWER: DePuy Defendants admit that certain DePuy Defendants have conducted business in the state of New York. DePuy Defendants deny that this Court has personal jurisdiction over Defendants DePuy International Limited, Johnson & Johnson and Johnson & Johnson Services, Inc. DePuy Defendants deny the remaining allegations contained in Paragraph 34.

35. Defendants assumed responsibility and continue to remain responsible for all legal obligations and liabilities, including personal injury and other tort claims, arising from the design, manufacture, test, inspection, distribution and sale of the Summit Tapered Hip System and stem.

ANSWER: Paragraph 35 contains legal conclusions to which no response is necessary. To the extent any response is required, DePuy Defendants deny the allegations in Paragraph 35. DePuy Defendants also deny that this Court has personal jurisdiction over Defendants DePuy International Limited, Johnson & Johnson and Johnson & Johnson Services, Inc.

36. Defendant Stryker Corporation is a corporation organized and existing under the laws of Michigan having its principal place of business located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 36. DePuy Defendants deny the allegations in paragraph 36 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 36.

37. Defendant Stryker Corporation is a resident of the State of Michigan.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37.

38. Defendant Stryker Corporation conducts business throughout the United States and has substantial contacts in, conducts substantial business in, and derives substantial revenue from its extensive activities within the State of New York.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 38.

39. At all relevant times, Stryker Corporation developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold Defendants' Defective Devices, either directly or indirectly, to members of the general public throughout the United States.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 39.

40. At all relevant times, Stryker Corporation was present and doing business in the State of New York and in the Southern District of New York in particular.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 40.

41. At all relevant times, Stryker Corporation transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41.

42. At all relevant times, Stryker Corporation expected or should have expected that its acts would have consequences with within the United States and in the Southern District of New York in particular.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 42.

43. Defendant Stryker Sales Corporation is corporation organized and existing under the laws of Michigan having its principal place of business located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 43.

44. Defendant Stryker Sales Corporation is a resident of the State of Michigan.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44.

45. Defendant Stryker Sales Corporation conducts business throughout the United States and has substantial contacts in, conducts substantial business in, and derives substantial revenue from its extensive activities within the State of New York.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 45.

46. Defendant Stryker Sales Corporation conducts business throughout the United States and has substantial contacts in, conducts substantial business in, and derives substantial revenue from its extensive activities within the State of New York.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 46.

47. At all relevant times, Stryker Sales Corporation developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold Defendants' Defective Devices, either directly or indirectly, to members of the general public throughout the United States.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 47.

48. At all relevant times, Stryker Sales Corporation was present and doing business in the State of New York and in the Southern District of New York in particular.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 48.

49. At all relevant times, Stryker Sales Corporation transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 49.

50. At all times, Stryker Sales Corporation expected or should have expected that its acts would have consequences within the United States and in the Southern District of New York in particular.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 50.

51. Defendant Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics, is a corporation organized and existing under the laws of New Jersey having its principal place of business located at 325 Corporate Drive, Mahwah, New Jersey 07430.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 51.

52. Defendant Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics is a resident of the State of New Jersey.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 52.

53. Defendant Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics conducts business throughout the United States and has substantial contacts in, conducts substantial business in, and derives substantial revenue from its extensive activities within the State of New York and in the Southern District of New York.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 53.

54. At all relevant times, Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold Defendants' Defective Devices, either directly or indirectly, to members of the general public throughout the United States

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 54.

55. At all relevant times, Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics was present and doing business in the State of New York and in the Southern District of New York in particular.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 55.

56. At all relevant times, Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics transacted, solicited, and conducted business in the State of New York and derived substantial revenue from such business.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 56.

57. At all relevant times, Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics expected or should have expected that its acts would have consequences within the United States, and in the Southern District of New York in particular.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 57.

58. At all relevant times, the employees of STRYKER CORPORATION, STRYKER SALES CORPORATION, and HOWMEDICA OSTEONICS CORP. d/b/a STRYKER ORTHOPAEDICS (hereinafter "STRYKER Defendants") and each of them, their subsidiaries, affiliates, and other related entities, as well as the employees of the defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of defendants STRYKER, such designations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of the defendants, and each of them, committed, knew of, performed, authorized, ratified and/or directed such transactions on behalf of defendants while actively engaged in the scope of their duties.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 58.

59. At all relevant times, each of the defendants were present and doing business in the State of New York in the Southern District of New York.

ANSWER: DePuy Defendants admit that certain DePuy Defendants have conducted business in the state of New York. DePuy Defendants deny the remaining allegations in Paragraph 59.

60. At all relevant times, each of the defendants transacted, solicited, and conducted business in the State of New York, and derived substantial revenue from such business.

ANSWER: DePuy Defendants admit that certain DePuy Defendants have conducted business in the state of New York. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 60 and therefore deny them.

61. At all relevant times, each of the defendants expected or should have expected that its acts would have consequences within the United States, and in the Southern District of New York in particular.

ANSWER: DePuy Defendants deny the allegations in paragraph 61.

III. JURISDICTION AND VENUE

62. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, as more fully set forth above, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

ANSWER: Paragraph 62 contains legal statements or conclusions to which no response is required.

63. This Court has supplemental jurisdiction over the common law and state claims pursuant to 28 U.S.C. § 1367.

ANSWER: Paragraph 63 contains legal statements or conclusions to which no response is required.

64. Plaintiffs reside in the State of Florida.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 64.

65. Plaintiffs are domiciled in the State of Florida.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 65.

66. Plaintiffs are citizens of the State of Florida.

ANSWER: DePuy Defendants admit that Plaintiffs allege that they are citizens of Florida for purposes of subject-matter jurisdiction.

67. No Defendant is a citizen of the same state as Plaintiffs.

ANSWER: DePuy Defendants admit that Plaintiffs allege that each defendant is a citizen of a state other than Florida for purposes of subject-matter jurisdiction.

68. The subject products were implanted in New York County, New York State.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 68.

69. Venue is proper in this district pursuant to 28 U.S.C. § 1961, et seq. because a substantial part of the events giving rise to this claim occurred in New York and this district.

ANSWER: Paragraph 69 contains legal statements or conclusions to which no response is required.

70. DEPUY Defendants are large companies, transacting and conducting business in the State of New York, including in the Southern District, by designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, advertising, marketing, distributing, and selling medical devices, including the Summit Tapered Hip System stem by Defendants supply the Summit Tapered Hip System stem to New York surgeons, hospitals and, of course, to the patients of those surgeons and hospitals.

ANSWER: DePuy Defendants admit that certain DePuy Defendants have conducted business in the state of New York. DePuy Defendants deny the remaining allegations in Paragraph 70. DePuy Defendants deny that this Court has personal jurisdiction over Defendants DePuy International Limited, Johnson & Johnson and Johnson & Johnson Services, Inc.

71. STRYKER Defendants are large companies, transacting and conducting business in the State of New York, including in the Southern District, by designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, advertising, marketing, distributing, and selling medical devices, including "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System by Defendants supply the "MDM®X3®" ADM/MDM System, "The Restoration " ADM/MDM System to New York surgeons, hospitals and, of course, to the patients of those surgeons and hospitals.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 71. DePuy Defendants deny the allegations in paragraph 71 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 71.

72. Defendants expected or should have expected that their acts would have consequences within the Southern District of New York, and derived substantial revenue from interstate commerce.

ANSWER: DePuy Defendants deny the allegations in paragraph 72. DePuy Defendants deny that this Court has personal jurisdiction over Defendants DePuy International Limited, Johnson & Johnson and Johnson & Johnson Services, Inc.

73. Defendants are further subject to *in personam* jurisdiction in the United States District Court for the Southern District of New York because they placed defective products in the stream of commerce there and the subject product was implanted there.

ANSWER: DePuy Defendants deny the allegations in paragraph 73 and deny that its products were defective in any way. DePuy Defendants deny that this Court has personal jurisdiction over Defendants DePuy International Limited, Johnson & Johnson and Johnson & Johnson Services, Inc.

IV. FACTUAL BACKGROUND

74. At all times mentioned in this complaint, the Depuy Defendants designed, developed, tested, manufactured, assembled, packaged, promoted, labeled, marketed, distributed and sold a hip replacement system, defective in its design, defective in its warnings, and defective in its manufacture, known as the Summit Tapered Hip System. The Summit Tapered Hip System and its stem component was sold to surgeons and hospitals in New York State and elsewhere, and implanted in thousands of patients, including Plaintiff.

ANSWER: DePuy Defendants admit that DePuy Orthopaedics, Inc. n/k/a Medical Device Business Services, Inc. designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System and its stem component. DePuy Defendants deny that the Summit Tapered Hip System is defective and deny the remaining allegations in Paragraph74.

75. At all times mentioned in this complaint, the STRYKER Defendants designed, developed, tested, manufactured, assembled, packaged, promoted, labeled, marketed, distributed and sold a hip replacement system, defective in its design, defective in its warnings, and defective in its manufacture, known as "MDM®X3®" ADM/MDM System, "The Restoration " ADM/MDM System was sold to surgeons and hospitals in New York State and elsewhere, and implanted in thousands of patients, including the Plaintiff.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 75. DePuy Defendants deny the allegations in paragraph 75 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 75.

76. At all times material, the Depuy Defendants owed a duty to the Plaintiff to assure that its product would be implanted in a medically safe manner including the use of all its own hip system parts.

ANSWER: Paragraph 76 contains legal statements or conclusions to which no response is required. To the extent that a response is required, DePuy Defendants deny the allegations in Paragraph 76.

77. At all times material, the DEPUY defendants knew or should have known that surgeons, including but not limited to Dr. Robert Buly, would mix and match components of various hip systems with other hip systems. The defendant failed to maintain accurate and reliable inventory and records that would have allowed the defendant to track the sales to particular hospitals and doctors and permit the tracking of uneven numbers of components of their hip system being used by hospitals thus preventing the tracking of the disproportionate use of the components of a particular hip system due to mixing and matching including the Depuy Summit Tapered Hip System.

ANSWER: DePuy Defendants deny the allegations in Paragraph 77.

78. At all times material, the Depuy defendants failed to provide adequate warning and or supervision of surgeons implanting these hip components and failed to establish an appropriate monitoring system to track the stock and inventory so that mix and match of different hip systems would and could not occur.

ANSWER: DePuy Defendants deny the allegations in Paragraph 78.

79. At all times material, the Stryker defendants owed a duty to the Plaintiff to assure that its product would be implanted in a medically safe manner including the use of all its own hip system parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 79. DePuy Defendants deny the allegations in paragraph 79 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 79.

80. At all times material, the Stryker defendants knew or should have known that surgeons, including but not limited to Dr. Robert Buly, would mix and match components of various hip systems with other hip systems, the defendant failed to maintain accurate and reliable inventory and records that would have allowed the defendant to track the sales to particular hospitals and doctors and permit the tracking of uneven numbers of components of their hip system being used by hospitals thus preventing the tracking of the disproportionate use of the components of a particular hip system due to missing and matching including the Stryker "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 80. DePuy Defendants deny the allegations in paragraph 80 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 80.

81. At all times material, the Stryker defendants failed to provide adequate warning and or supervision of surgeons implanting these hip components and failed to establish an appropriate monitoring system to track the stock and inventory so that mix and match of different hip systems would and could not occur.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 81. DePuy Defendants deny the allegations in paragraph 81 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 81.

THE SUMMIT TAPERED HIP SYSTEM

82. First marketed and sold prior to 2012, Defendants developed the Summit Tapered Hip System in order to reconstruct human hip joints that are diseased due to conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, or fracture. The hip joint connects the thigh or femur bone of the leg to the pelvis. The hip joint resembles a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

ANSWER: DePuy Defendants admit that the allegations in Paragraph 82 concerning the hip joint are generally accurate. DePuy Defendants deny the remaining allegations in Paragraph 82.

83. The Summit total hip replacement implant device consists of four separate components: a femoral stem; a femoral head or ball; a liner; and an acetabular shell or socket. The Stryker MDM consists of four separate parts. In Plaintiffs total hip replacement the femoral stem was the Depuy Summit stem un cemented stem size #1 high offset 125mm component; the Head was a Depuy Biolox delta art cam HD 28+5 mm, along with "*a Stryker acetabular* shell HA cluster hemi 52mm; *Stryker* ADM x328/48 *polyethelene insert*, " (Source: Operative Report of Index Surgery).

ANSWER: DePuy Defendants deny the allegations in Paragraph 83 directed against them. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 83.

84. Defendants marketed and described the Summit Device as "uniquely designed to meet the demands of active patients like you - and help reduce pain."

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 84.

85. Defendants advertised and sold the Summit Device as the best surgical option that *"recreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."*

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 85.

86. Defendants sold over 100,000 Summit Devices. Defendants stated in Promotional materials that "99.9% of Summit hip components are still in use today."

ANSWER: DePuy Defendants deny the allegations in Paragraph 86 as phrased.

87. Over 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration (FDA) regarding failure or complications of the Summit Devices.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 86.

88. Defendants have long been aware, including before Plaintiffs receipt of her Summit, that Summit Devices may result in metallosis, biologic toxicity and high failure rate. The Summit Device, when implanted, results unsafe release of toxic metal particles and ions into hip implant recipients' tissue and bloodstream. Plaintiff further alleges that Defendants were and continue to be aware that the metal particles from Summit Devices results in metallosis, tissue death and bone erosion.

ANSWER: DePuy Defendants deny the allegations in Paragraph 88.

89. Plaintiff alleges that particulate debris from the Summit Devices causes severe inflammation, severe pain, tissue and bone loss, and other related diseases and medical issues.

ANSWER: DePuy Defendants deny the allegations in Paragraph 89

90. Plaintiff further alleges that, at all relevant times, Defendants were and continue to be aware that Summit Device recipients have elevated titanium, aluminum, and other metals levels and exposure to hydroxyapatite, and other textures and coatings greatly exceeding acceptable safety standards.

ANSWER: DePuy Defendants deny the allegations in Paragraph 90.

91. Plaintiff was a recipient of a hip replacement with the Summit Device stem, and has suffered permanent injuries, pain and suffering, economic loss and disability.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 91 and therefore deny them.

92. The Summit Device consists of four discrete parts or components that connect: a metal femoral stem; consisting of Titanium, Aluminum, and other metals, and hydroxyapatite, and other textures and coatings, a polymel femoral head ("ball"); a liner (half dome shaped and made of cobalt/chromium); and a "cup" that fits into the acetabulum, the so-called "socket" of the hip. Only the stem was used in this case.

ANSWER: DePuy Defendants admit that Plaintiffs' allegations in Paragraph 92 concerning the components of the Summit Device are generally correct. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 92 and therefore deny them.

DEFENDANTS DEPUY CLEARED SUMMIT TAPERED HTP SYSTEM AS A CLASS II DEVICE WITHOUT PRE-MARKET APPROVAL

93. In 1976, the Medical Devices Amendment ("MDA") was enacted, pursuant to which the United States Food and Drug Administration ("FDA") has classified medical devices into three categories. A Class I category device poses almost no safety issues. A Class II category device poses moderate safety issues. A Class III device operates to sustain human life, is of substantial importance in preventing impairment of human health, or poses potentially unreasonable risks of harm to patients.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 93, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 93.

94. Generally, Class III devices must undergo the Premarket Approval (PMA) process to be marketed in the United States. Premarket Approval is a rigorous review process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, extensive clinical data to support the device's safety and effectiveness; a full statement of the device's components, ingredients, and properties, and principles of operation; a full description of the methods

used in, and the facilities and controls used for, the design, manufacture, processing, and when relevant, packing and installation of such device; samples or device components required by the FDA; and a specimen of the proposed labeling. When undergoing Premarket Approval, a Class III device may not use an existing device as a predicate. Rather, the safety and effectiveness of the device must be independently shown.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 94, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 94.

95. As the United States Supreme Court describes it, Premarket Approval is a "rigorous" process. A manufacturer must submit what is typically a multi volume application. *See, FDA, Device Advice—Premarke (Approval (PM A) 18*, http://www.fda.gov/cdrhldevadvice/pmalprinter.htm. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. 21 U.S.C. §360e(c)(l). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts. 21 C.F.R. § 814.44(a) (2007). The panel may request additional data from the manufacturer. 21 U.S.C. § 360e(c)(I)(G). The FDA spends an average of 1,200 hours reviewing each application,

and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e(d). The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). *Riegel v. medtronic, Inc*., 552 U.S. 312, 317-318 (2008). The FDA may grant Premarket Approval only upon a finding that there is reasonable assurance that the medical device is safe and effective, and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 95, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 95.

96. However, devices were formally classified into Class III. Nonetheless, because these Class III devices predate the MDA, and because the FDA has neither called for Pre-market Approval to be requested nor downwardly classified these devices, these hip systems avoided the rigorous scrutiny of the Pre-market Approval Process. Instead, they were and are "grandfathered in" and cleared for sale through manufacturers' demonstration of substantial equivalence to other "predicate" systems previously on the market. This is the Premarket Notification or "510(k) process" by which Class II devices, ostensibly less dangerous, are cleared for market.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 96, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the

DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 96.

97. The Summit Tapered Hip System stem which is the subject of this lawsuit should have undergone the Premarket Approval process for Class III medical devices.

ANSWER: DePuy Defendants deny the allegations in Paragraph 97.

98. However, Defendants received clearance of the Summit Tapered Hip System including stem from the FDA through the 510(k) process which is generally reserved for Class II devices. The 510(k) process only requires a showing of substantial equivalence to a device previously on the market. The FDA spends approximately twenty hours on this review process. *See, Adesina v. Aladan Corp*., 438 F.Supp.2d 329, 334 (S.D.N.Y. 2006).

ANSWER: DePuy Defendants admit only that the FDA cleared the Summit Tapered Hip System for sale in the United States pursuant to the 510(k) process, which is governed by federal regulations that speak for themselves. DePuy Defendants deny the remaining allegations in Paragraph 98.

99. In obtaining clearance for marketing of the Summit Tapered Hip System and stem through the 510(k) process, Defendants made an end run around and bypassed the rigorous Premarket Approval process altogether.

ANSWER: DePuy Defendants admit only that the FDA cleared the Summit Tapered Hip System for sale in the United States pursuant to the 510(k) process, which is governed by

federal regulations that speak for themselves. DePuy Defendants deny the remaining allegations in Paragraph 99 as phrased and inaccurately and incompletely presented.

100. The Summit Tapered Hip System did not receive Premarket Approval from the FDA.

ANSWER: The FDA cleared the Summit Tapered Hip System for sale in the United States pursuant to the 510(k) process. DePuy Defendants deny as phrased and incompletely and inaccurately presented the remaining allegations contained in Paragraph 100.

101. The Defendants did not seek Pre-Market Approval from the FDA for the Summit System.

ANSWER: The FDA cleared the Summit Tapered Hip System for sale in the United States pursuant to the 510(k) process. DePuy Defendants deny as phrased and incompletely and inaccurately presented the remaining allegations contained in Paragraph 101.

102. The Defendants conducted no clinical trials of the Summit Device before first marketing and selling it in the early part of last decade. Defendant placed the Summit Device into the stream of commerce with deliberate willful blindness to the existence of it dangerousness to patients.

ANSWER: DePuy Defendants deny the allegations contained in Paragraph 102.

103. Clinical trials, if performed, would have demonstrated that Summit Device recipients developed metallosis and experienced failure of their hip replacements at a higher than expected rate, one exceeding acceptable rates in the industry. The trials

would have also demonstrated a higher than expected, and unreasonably dangerous, incidence of elevated blood metal ion levels. The human body, for example, should not have any measurable titanium nor hydroxyapatite in the blood.

ANSWER: DePuy Defendants deny the allegations in Paragraph 103.

104. The Summit Device is unreasonably dangerous in that its titanium make up and hydroxyapatite (HA) coating components, the femoral head and the liner, interface and resulting friction from ordinary and expected usage of the device, such as walking, cause "fretting" and the release of metal particles. Hydroxyapatite (HA) crystals are known cause musculo-skeletal inflammation and significant joint destruction.

ANSWER: DePuy Defendants deny the allegations in Paragraph 104.

105. The release of Titanium, Aluminum, and other metals, and hydroxyapatite, and other textures and coatings, results in pain, swelling, inflammation, local and systemic adverse tissue reactions, inflammatory reactions secondary to wear particle toxicity, host immunological hypersensitivity, alters cell function, causes permanent genomic instability, damages capillaries, decreases collagen fibers, elicits a biological response, metallosis, necrosis of bone, muscle and other tissues, with a decrease in range of motion.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 105, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 105.

106. The performance of the Summit Device is akin to other predecessor hip systems that have been recalled globally, for reasons substantially similar to the hazards of the Summit Device.

ANSWER: DePuy Defendants deny the allegations in Paragraph 106.

107. The devices share more than shoddy performance.

ANSWER: DePuy Defendants deny the allegations in Paragraph 107.

108. The FDA has received hundreds of adverse reports concerning the Summit Device.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 108 and therefore deny them.

109. In 1996, Jonathan Black, Ph.D., an industry consultant and Clemson University professor emeritus of bioengineering specializing in production and biological sequelae of wear debris, warned in a medical journal article that these hip designs posed significant risks because little was known of the biological damage that metallic debris might cause. Dr. Black also argued that, given the high success rate of existing designs, it would be statistically impossible to run enough studies to prove the new implants' supposed superiority.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 109, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 109.

110. On November 1, 2001, in *The Journal of Bone and Joint Surgery* 83:S68-72, Dr. Seth Greenwald and Dr. Jonathan Garino echoed Professor Black's concerns regarding the long-term effects of metal particle and ion generation, citing increased chromium concentrations found in McKee-Farrar implant recipients who were followed in multiyear studies.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 110, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 110.

111. In 2003, the British Journal of Bone and Joint Surgery reported the work of Clarke, Lee, Arora and Villar who found that large diameter metal-on-metal bearings result in greater systemic exposure of the device recipients to cobalt and chromium ions.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 111, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 111.

112. In July 2005, *The Journal of Bone and Joint Surgery* published the results of a study that retrospectively analyzed 165 patients (169 hips) who had undergone primary cementless total hip replacement with contemporary total hip replacement designs. The findings of the study raised concern that early osteolysis in patients with second generation hip replacement systems is associated with abnormalities consistent with delayed-type metal hypersensitivities.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 112, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 112.

113. The formation of metallosis, pseudotumors, infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and lack of mobility. These formations further render revision surgery exponentially more difficult to perform, with a higher risk for dislocation post-surgery and a worse probability for success, and in some cases the complete removal of the hip known as a Girdlestone.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 113, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 113.

114. At all relevant times, Defendants were aware that the Summit Tapered Hip System stem posed an unreasonably high risk of causing metallosis, biologic toxicity, and total hip failure. Defendants were aware that the Summit Tapered Hip System resulted in unsafe release of toxic metal particles and ions into the tissues and bloodstream of the recipients.

ANSWER: DePuy Defendants deny the allegations in paragraph 114.

DEFENDANTS STRYKER CLEARED ' THE "MDM®X3®" ADM/MDM SYSTEM. "THE RESTORATION®" ADM/MDM SYSTEM AS A CLASS II DEVICE WITHOUT PRE MARKET APPROVAL

115. In 1976, the Medical Devices Amendment ("MDA") was enacted, pursuant to which the United States Food and Drug Administration ("FDA") has classified medical devices into three categories. A Class I category device poses almost no safety issues. A Class II category device poses moderate safety issues. A Class III device operates to sustain human life, is of substantial importance in preventing impairment of human health, or poses potentially unreasonable risks of harm to patients.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 115. DePuy Defendants deny the allegations in paragraph 115 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 115.

116. Generally, Class III devices must undergo the Premarket Approval (PMA) process to be marketed in the United States. Premarket Approval is a rigorous review process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, extensive clinical data to support the device's safety and effectiveness; a full statement of the device's components, ingredients, and properties, and principles of operation; a full description of the methods used in, and the facilities and controls used for, the design, manufacture, processing, and when relevant, packing and installation of such device; samples or device components required by the FDA; and a specimen of the proposed labeling. When undergoing

Premarket Approval, a Class III device may not use an existing device as a predicate. Rather, the safety and effectiveness of the device must be independently shown.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 116. DePuy Defendants deny the allegations in paragraph 116 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 116.

117. As the United States Supreme Court describes it, Premarket Approval is a "rigorous" process. A manufacturer must submit what is typically a multivolume application. *See*, *FDA, Device Advice--Premarket Approval (PMA) 18,* http://www.fda.gov/cdrhldevadvice/pmalprinter.htm. It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. 21 U.S.C. §360e(c)(l). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts. 21 C.F.R. § 814.44(a) (2007). The panel may request additional data from the manufacturer. 21 U.S.C. § 360e(c)(I)(G). The FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness." 21 U.S.C. § 360e(d). The agency must "weig[h] any

probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). *Riegel v. medtronic*, Inc., 552 U.S. 312, 317-318 (2008). The FDA may grant Premarket Approval only upon a finding that there is reasonable assurance that the medical device is safe and effective, and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 116. DePuy Defendants deny the allegations in paragraph 117 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 117.

118. Nonetheless, because these Class III devices predate the MDA, and because the FDA has neither called for Pre market Approval to be requested nor downwardly classified these devices, metal-on-metal hip systems avoided the rigorous scrutiny of the Pre market Approval Process. Instead, they were and are "grandfathered in" and cleared for sale through manufacturers' demonstration of substantial equivalence to other "predicate" systems previously on the market. This is the Premarket Notification or "510(k) process" by which Class II devices, ostensibly less dangerous, are cleared for market.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 118. DePuy Defendants deny the allegations in paragraph 118 to the extent they are directed against DePuy Defendants. DePuy

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 118.

119. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System which is the subject of this lawsuit should have undergone the Premarket Approval process for Class III medical devices.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 119. DePuy Defendants deny the allegations in paragraph 119 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 119.

120. However, Defendants received clearance of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System from the FDA through the 510(k) process which is generally reserved for Class II devices. The 510(k) process only requires a showing of substantial equivalence to a device previously on the market. The FDA spends approximately twenty hours on this review process. *See, Adesina v. Aladan Corp*., 438 F.Supp.2d 329, 334 (S.D.N.Y. 2006).

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 120. DePuy Defendants deny the allegations in paragraph 120 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 120.

121. In obtaining clearance for marketing of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System through the 510(k) process, Defendants made an end run around and bypassed the rigorous Premarket Approval process altogether.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 121. DePuy Defendants deny the allegations in paragraph 121 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 121.

122. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System did not receive Premarket Approval from the FDA.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 122. DePuy Defendants deny the allegations in paragraph 122 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 122.

123. The Defendants did not seek Pre-Market Approval from the FDA for the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 123. DePuy Defendants deny the allegations in paragraph 123 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 123.

124. The Defendants conducted no clinical trials of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System before first marketing and selling it in the early part of this decade (2011). Defendant placed the Summit Device into the stream of commerce with deliberate willful blindness to the existence of it dangerousness to patients.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 124. DePuy Defendants deny the allegations in paragraph 124 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 124.

125. Clinical trials, if performed, would have demonstrated that "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System Device recipients developed metallosis and experienced failure of their hip replacements at a higher than expected rate, one exceeding acceptable rates in the industry. The trials would have also demonstrated a higher than expected, and unreasonably dangerous, incidence of elevated blood metal levels. The human body, for example, should not have any measurable cobalt ions in the blood.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 125. DePuy Defendants deny the allegations in paragraph 125 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 125.

126. The "The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System is unreasonably dangerous in that its cobalt and chromium components, the femoral head and the liner, interface. The resulting friction from ordinary and expected usage of the device, such as walking, causes "fretting" and the release of metal particles.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 126. DePuy Defendants deny the allegations in paragraph 126 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 126.

127. The release of cobalt and chromium particles results in pain, swelling, inflammation, adverse tissue reactions, metallosis, necrosis of bone, muscle and other tissues, with a decrease in range of motion.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 127. DePuy Defendants deny the allegations in paragraph 127 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 127.

128. The formation of metallosis, pseudotumors, infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and lack of mobility. These formations further render revision surgery exponentially more difficult to perform.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 128. DePuy Defendants deny the allegations in paragraph 128 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 128.

129. At all relevant times, Defendants were aware that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System posed an unreasonably high risk of causing metallosis, biologic toxicity, and total hip failure. Defendants were aware that the "The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System resulted in unsafe release of toxic metal ions into the tissues and bloodstream of the recipients.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 129. DePuy Defendants deny the allegations in paragraph 129 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 129.

THE FAILURE OF PLAINTIFF'S SUMMIT DEVICE

130. Mrs. Rouviere suffers from degeneration of the right hip joint subsequent to an orthopaedic injury.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 130 and therefore deny them.

131. On August 12, 2012, Plaintiff underwent a total right hip replacement at New York's Hospital for Special Surgery. Robert Buly, M.D., an orthopedic surgeon, performed the surgery. He implanted a Summit Tapered Hip System Stem into plaintiff's right hip.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 131 and therefore deny them.

132. Dr. Buly implanted the subject product in accordance with instructions, directions and other information made available by the Defendants, the manufacturers and designers.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 132 and therefore deny them.

133. Plaintiff followed all post-operative instructions from her physicians, and made limited improvements in her ability to walk, move her right leg, and regain range of motion.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 133 and therefore deny them.

134. Post-operatively, Ms. Rouviere's Summit Tapered Hip System stem failed. By the beginning of 2013, she experienced pain and loss of range of motion.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 134 and therefore deny them.

135. Blood testing performed in May of 2015 demonstrated highly elevated Chromium level of .9 MUG/L- Arsenic of MUG/L 5 and neither cobalt nor titanium was not tested for at that time. In December 2016 , one month after the removal of the defective hip, the Cobalt level was .6 MCG/L and chromium was < .2 MCG/L.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 135 and therefore deny them.

136. Mrs. Rouviere underwent revision surgery on November 11, 2016. The diagnosis given by the Dr. Carlos Alvarado, MD was "ASEPTIC INFLAMMATORY FAILURE, RIGHT HIP ARTHROPLASTY."

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 136 and therefore deny them.

137. "*Black metallic prosthetic particles*" were ascertained by pathology studies of excised tissue with pathology reports of "Synovium and subsynovial connective tissue with pigment deposition, papillary hyperplasia, fibrosis and fibrin deposition."

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 137 and therefore deny them.

138. Plaintiffs Summit Tapered Hip System stem visibly deteriorated, released and releases metal particles, including hydroxyapatite and other coatings and textures, from its surface.

ANSWER: DePuy Defendants deny the allegations in Paragraph 138.

139. Plaintiffs Summit Tapered Hip System stem deteriorated, and released and releases Titanium from its interior.

ANSWER: DePuy Defendants deny the allegations in Paragraph 139.

140. Plaintiffs Summit Tapered Hip System stem deteriorates, and released and releases titanium, Aluminum and hydroxyapatite and other coatings and textures applied that cause galvanic corrosion within the patient.

ANSWER: DePuy Defendants deny the allegations in Paragraph140.

141. Plaintiffs Summit Tapered Hip System stem deteriorated, and released and releases Aluminum and other metals from its interior.

ANSWER: DePuy Defendants deny the allegations in Paragraph 141.

142. Plaintiffs elevated blood metal ion level resulted directly from the deterioration of the Summit Tapered Hip System stem.

ANSWER: DePuy Defendants deny the allegations in Paragraph 142

143. Studies published prior to the Plaintiffs implant in 2012 have shown that exposure to Titanium, Aluminum and other metals, hydroxyapatite and other coatings and textures applied can cause severe inflammatory reaction secondary to wear particle debris and/or host immunological sensitivity.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 143, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the

DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 143.

144. The U.S. Department of Health and Human Services/Agency for Toxic Substances and Diseases Registry ("ATSDR") issues toxicological profiles for Titanium, Aluminum and other metals, hydroxyapatite and other coatings and textures.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 144, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 144.

145. According to the ATSDR, absorption of excess metal, including titanium, and Aluminum and other metals results in causing an inflammatory reaction effects to the respiratory, cardiovascular, gastrointestinal, hematological, hepatic, renal, endocrine, dermal, and ocular systems. Cardiomyopathy, damage to nerves, and dysfunctional blood clotting may result.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 145, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 145.

146. According to the ATSDR, absorption of excess chromium results in renal failure, hemolysis, liver damage, multiple organ failure and death.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 146, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 146.

147. Plaintiff does not suffer and has not suffered from occupational exposure to titanium.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 147 and therefore deny them.

148. Plaintiff does not suffer and has not suffered from occupational exposure to aluminum.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 148 and therefore deny them.

149. Plaintiff does not ingest and has not ingested, orally or through inhalation, Titanium and/or Aluminum and other metals

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 149 and therefore deny them.

150. Plaintiff does not ingest and has not ingested, orally or through inhalation, Cobalt and/or Chromium and other metals

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 150 and therefore deny them.

151. Plaintiff has no source of exposure to Cobalt and/or Chromium and other metals that would account for her elevated blood metal ion levels other than the subject product.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 151 and therefore deny them.

152. Plaintiff has no source of exposure to Titanium and/or Aluminum and other metals that would account for her elevated blood metal ion levels other than the subject product.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 152 and therefore deny them.

153. An appropriate, safe, competently and reasonably designed hip implant should not deteriorate prematurely and will not corrode nor release Titanium and/or Aluminum and other metals into the human body.

ANSWER: DePuy Defendants deny that its product was defective in any way and deny as phrased and incompletely and inaccurately presented the remaining allegations contained in Paragraph 153.

154. An appropriate, safe, competently and reasonably designed hip implant should not deteriorate prematurely and will not corrode nor release Cobalt and/or Chromium and other metals into the human body.

ANSWER: DePuy Defendants deny that its product was defective in any way and deny as phrased and incompletely and inaccurately presented the remaining allegations contained in Paragraph 154.

155. Unreasonably dangerous hip implants, as designed, will deteriorate prematurely, corrode and release Titanium and/or Aluminum and other metals into the human body.

ANSWER: DePuy Defendants deny that its product was defective in any way and deny as phrased and incompletely and inaccurately presented the remaining allegations contained in Paragraph 155.

156. Unreasonably dangerous hip implants, as designed, will deteriorate prematurely, corrode and release Cobalt and/or Chromium and other metals into the human body.

ANSWER: DePuy Defendants deny that its product was defective in any way and deny as phrased and incompletely and inaccurately presented the remaining allegations contained in Paragraph 156.

157. An appropriate, safe, competently and reasonably manufactured hip implant should not and will not corrode and deteriorate prematurely releasing Titanium and/or Aluminum and other metals into the human body.

ANSWER: DePuy Defendants deny that its product was defective in any way and deny as phrased and incompletely and inaccurately presented the remaining allegations contained in Paragraph 157.

158. An appropriate, safe, competently and reasonably manufactured hip implant should not and will not corrode and deteriorate prematurely releasing Cobalt and/or Chromium and other metals into the human body.

ANSWER: DePuy Defendants deny that its product was defective in any way and deny as phrased and incompletely and inaccurately presented the remaining allegations contained in Paragraph 158.

159. Unreasonably dangerous hip implants, as manufactured, will corrode and deteriorate prematurely and release Cobalt and/or Chromium and other metals into the human body.

ANSWER: DePuy Defendants deny that its product was defective in any way and deny as phrased and incompletely and inaccurately presented the remaining allegations contained in Paragraph 159.

160. Unreasonably dangerous hip implants, as manufactured, will corrode and deteriorate prematurely and release Titanium and/or Aluminum and other metals into the human body.

ANSWER: DePuy Defendants deny that its product was defective in any way and deny as phrased and incompletely and inaccurately presented the remaining allegations contained in Paragraph 160.

161. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unreasonably dangerous in design in that it deteriorated prematurely, corroded and released and releases Cobalt and/or Chromium and other metals into the human body, including Plaintiffs body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 161. DePuy Defendants deny the

allegations in paragraph 161 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 161.

162. The Defendants' Summit Tapered Hip System stem was unreasonably dangerous in design in that it deteriorated prematurely, corroded and released and releases Titanium and/or Aluminum and other metals into the human body, including Plaintiffs body.

ANSWER: DePuy Defendants deny that its product was defective in any way and deny any remaining allegations in Paragraph 162.

163. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unreasonably dangerous in manufacture in that it deteriorated prematurely, corroded and released and releases Cobalt and/or Chromium and other metals into the human body, including Plaintiffs body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 163. DePuy Defendants deny the allegations in paragraph 163 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 163.

164. The Defendants' Summit Tapered Hip System stem was unreasonably dangerous in manufacture in that it deteriorated prematurely, corroded and released and releases Titanium and/or Aluminum and other metals into the human body, including Plaintiffs body.

ANSWER: DePuy Defendants deny that its product was defective in any way and deny any remaining allegations in Paragraph 164.

165. "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System corroded and deteriorated with usage under normal, ordinary and foreseeable conditions, resulting in the release of Cobalt and/or Chromium and other metals into the surrounding tissue, blood and organs of the recipient.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 165. DePuy Defendants deny the allegations in paragraph 165 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 165.

166. As manufacturers of hip replacement systems, the Defendants had the legal duty to warn physicians of the risk of corrosion and deterioration of the respective Hip Systems, the risk that the system's composition, including Cobalt and/or Chromium, Titanium and/or Aluminum and other metals, would corrode and deteriorate and release Cobalt and/or Chromium, Titanium and/or Aluminum and other metals into the surrounding tissue, blood, and organs of the patient.

ANSWER: DePuy Defendants state that the allegations in Paragraph 166 regarding duty constitute conclusions of law to which no response is required. To the extent a response is required, to the extent Defendants owed a duty, they satisfied that duty. DePuy Defendants deny any remaining allegations in Paragraph 166.

167. The Summit Tapered Hip System stem came with no warning whatsoever that its usage under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and the release of Titanium and/or Aluminum and other metals from its component parts.

ANSWER: DePuy Defendants deny the allegations in Paragraph 167.

168. "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no warning whatsoever that its usage under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and the release of Cobalt and/or Chromium and other metals from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 168. DePuy Defendants deny the allegations in paragraph 168 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 168.

169. The Summit Tapered Hip System stem came with no warning whatsoever that its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and in elevated Titanium and/or Aluminum and other metals levels in the human body.

ANSWER: DePuy Defendants deny the allegations in Paragraph 169.

170. "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no warning whatsoever that its usage, including the usage of its component

parts, under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and in elevated Cobalt and/or Chromium and other metals levels in the human body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 170. DePuy Defendants deny the allegations in paragraph 170 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 170.

171. The Summit Tapered Hip System stem came with no written information that one of the adverse effects of usage under normal, ordinary and foreseeable conditions would be its corrosion and deterioration and the release of Titanium and/or Aluminum and other metals from its component parts.

ANSWER: DePuy Defendants deny the allegations in Paragraph 171.

172. "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no written information that one of the adverse effects of usage under normal, ordinary and foreseeable conditions would be its corrosion and deterioration and the release of Cobalt and/or Chromium and other metals from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 172. DePuy Defendants deny the allegations in paragraph 172 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 172

173. The Summit Tapered Hip System stem came with no written information whatsoever that an adverse effect of its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would be corrosion and deterioration with resulting elevated Titanium and/or Aluminum and other metals levels in the human body.

ANSWER: DePuy Defendants deny the allegations in Paragraph 173.

174. "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no written information whatsoever that an adverse effect of its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would be corrosion and elevated Cobalt and/or Chromium and other metals levels in the human body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 174. DePuy Defendants deny the allegations in paragraph 174 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 174.

175. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the Summit Tapered Hip System stem and its component parts had they known that it usage under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and the release of Titanium and/or Aluminum and other metals from its component parts.

ANSWER: DePuy Defendants deny the allegations in Paragraph 175.

176. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and the release of Cobalt and/or Chromium and other metals from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 176. DePuy Defendants deny the allegations in paragraph 176 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 176.

177. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the Summit Tapered Hip System stem and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and elevated levels of Titanium and/or Aluminum and other metals in patients receiving the implant.

ANSWER: DePuy Defendants deny the allegations in Paragraph 177.

178. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and elevated levels of Cobalt and/or Chromium and other metals in patients receiving the implant.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 178. DePuy Defendants deny the allegations in paragraph 178 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 178.

179. Defendants failed to advise Plaintiffs implanting surgeon that the usage of Summit System stem under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and the release of Titanium and/or Aluminum and other metals from its component parts.

ANSWER: DePuy Defendants deny the allegations in Paragraph 179.

180. Defendants failed to advise Plaintiffs implanting surgeon that the usage of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and the release of Cobalt and/or Chromium and other metals from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 180. DePuy Defendants deny the allegations in paragraph 180 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 180.

181. Defendants failed to advise Plaintiffs implanting surgeon that the usage of Summit System under normal, ordinary and foreseeable conditions would result in

corrosion and elevated Titanium and/or Aluminum and other metals levels in the human body.

ANSWER: DePuy Defendants deny the allegations in Paragraph 181.

182. Defendants failed to advise Plaintiffs implanting surgeon that the usage of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System under normal, ordinary and foreseeable conditions would result in corrosion and elevated Cobalt and/or Chromium and other metals levels in the human body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 182. DePuy Defendants deny the allegations in paragraph 182 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 182.

183. Robert Buly, M.D. would not have selected the Summit Tapered Hip System stem had he known that its usage under normal, ordinary and foreseeable conditions would result in the corrosion and release of Titanium and/or Aluminum and other metals from its component parts.

ANSWER: DePuy Defendants deny the allegations in Paragraph 183.

184. Robert Buly, M.D. would not have selected "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in the corrosion and release of Cobalt and/or Chromium and other metals from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 184. DePuy Defendants deny the allegations in paragraph 184 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 184.

185. Robert Buly, M.D. would not have selected the Summit Tapered Hip System stem and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in corrosion and elevated levels of Titanium and/or Aluminum and other metals in patients receiving the implant, including Plaintiff.

ANSWER: DePuy Defendants deny the allegations in Paragraph 185.

186. Robert Buly, M.D. would not have selected the Summit Tapered Hip System stem and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in corrosion and elevated exposure to hydroxyapatite, and other textures and coatings, in patients receiving the implant, including, Plaintiff Mrs. Rouviere.

ANSWER: DePuy Defendants deny the allegations in Paragraph 186.

187. The FDA panel did not find that the Summit systems provided significant benefits to the thousands of American patis who rely on them.

ANSWER: DePuy Defendants deny the allegations in Paragraph 187.

188. Defendants did not have adequate and appropriate systems in place to collect and analyze any of the complaints they received from doctors, hospitals, and/or patients concerning the Summit Tapered Hip System stem, as required by the FDA, thus leading to inconsistencies and irregularities in the way defendants kept track of complaints they received regarding the failure of the Summit System.

ANSWER: DePuy Defendants deny the allegations in Paragraph 188.

189. Defendants knew, or should have known, of the seriousness of the risks of using the Summit Tapered Hip System stem, based upon the state of knowledge of the Summit Tapered Hip System, as it existed at that time, and upon generally accepted medical and research standards and principles.

ANSWER: DePuy Defendants deny the allegations in Paragraph 189.

190. Defendants knew, or should have known, of the seriousness of the risks of using the Summit Tapered Hip System stem based upon the complaints they received from doctors, hospitals, and/or patients who used the Summit Tapered Hip System demonstrating that the product was defective and defendant failed to properly warn of the propensity of the Summit Stem System to given did not accurately reflect the symptoms, or severity of the side effects including but not limited to shedding of titanium, aluminum, and other metals levels and exposure to hydroxyapatite, and other textures and coatings in a recipients body including the plaintiff.

ANSWER: DePuy Defendants deny the allegations in Paragraph 190.

191. Defendants failed to send the necessary product failure reports to the FDA, as required by the FDA, indicating that the failure rate of Summit Tapered Hip System and its stem was higher than the generally accepted standard rate of failure in the industry.

ANSWER: DePuy Defendants deny the allegations in Paragraph 191.

192. Defendants failed to appropriately and adequately warn the Plaintiff and/or her physicians, hospitals, and/or the FDA, of the serious and dangerous risks involved in using Defendants' Summit Tapered Hip System stem including, but not limited to, the possibility of the shedding of titanium, aluminum, and other metals levels and exposure to hydroxyapatite, and other textures and coating, corrosion, poisoning, fretting, severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants deny the allegations in Paragraph 192.

193. Defendants misrepresented the known risks inherent in the use of the Summit Tapered Hip System and its stem.

ANSWER: DePuy Defendants deny the allegations in Paragraph 193.

194. Defendants made certain claims which were distributed and circulated to the medical and healthcare professions that the Summit Tapered Hip System and its stem were safe.

ANSWER: DePuy Defendants deny the allegations in Paragraph 194.

195. Defendants were careless and negligent in the manufacturing, testing, selling, distribution, merchandising, advertising, marketing, promotion, compounding, packaging, fabrication, warning, analyzing, marketing, and recommendation of the Summit Tapered Hip System and its stem.

ANSWER: DePuy Defendants deny the allegations in Paragraph 195.

196. By reason of the foregoing, Plaintiff has suffered and/or is at an extremely high risk of suffering serious and dangerous side effects, including but not limited to severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants deny the allegations in Paragraph 196.

197. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has and/or may suffer serious and dangerous side effects as a result of her Summit Tapered Hip System and its stem. Plaintiff suffers from elevated blood metal levels and has had to undergo surgical explantation of her prosthetic hip and/or components. The plaintiff lives without one hip.

ANSWER: DePuy Defendants deny the allegations in Paragraph 197.

198. By reason of the foregoing, Plaintiff has been severely and permanently injured and/or has been exposed to risk of severe and permanent injury, and has and will require more constant and continuous medical monitoring and treatment than prior to her implantation of Defendants' Summit Tapered Hip System and its stem.

ANSWER: DePuy Defendants deny the allegations in Paragraph 198.

199. Moreover, "Medical devices in general, not just Class III devices, are subject to the FDA's current good manufacturing practice requirements (CGMP requirements). 21 U.S.C.§ 360j(f); 21 C.F.R. § 820 et seq. These requirements set forth a quality control system and "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R § 820.1(a)(1). They are in place "to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." 21 C.F.R. § 820.1(a)(1). To comply with the CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. § 820.1-.250. By requiring manufacturers to adopt a variety of procedures and controls, "[t]he CGMP requirements ... leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. § 820.1-.250. By requiring manufacturers to adopt a variety of procedures and controls, "[t]he CGMP requirements ... leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective." *Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271, 279 (E.D.N.Y. 2009), *Gelber v. Stryker Corp.*, 788 F.Supp.2d 145, 152 (S.D.N.Y. 2011).

ANSWER: DePuy Defendants make no response to rhetorical paragraph 199, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the

DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 199.

200. In designing, developing, testing, manufacturing, assembling, packaging, promoting, labeling, marketing, distributing and selling the Summit Tapered Hip System, and stem Defendants violated CGMP requirements for the reasons set forth above, including the deterioration of the metal stem.

ANSWER: DePuy Defendants deny the allegations in Paragraph 200.

201. Defendants knowingly and deliberately made material misrepresentations to the FDA concerning the design, manufacture, safety, and efficacy of Defendants' Summit Tapered Hip System and its stem was a Section 510(k) medical device.

ANSWER: DePuy Defendants deny the allegations in Paragraph 201.

202. Defendants' claims to the FDA, that Defendants' Summit Tapered Hip System and its stem was substantially equivalent to predicate devices marketed prior to May 28, 1976, misled the FDA and the consuming public.

ANSWER: DePuy Defendants deny the allegations in Paragraph 202.

203. By marketing Defendants' Summit Tapered Hip System and its stem, as Section 510(k) medical device, Defendants were able to avoid conducting any formal review or undertaking any study of the products' safety or efficacy.

ANSWER: DePuy Defendants deny the allegations in Paragraph 203.

204. Defendants' Summit Tapered Hip System and its stem was designed, patented, manufactured, labeled, marketed, and sold and distributed by Defendants, at all times relevant herein to the medical community and to patients as: safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of patients undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of osteoarthritis and other conditions and/or diseases; and as safer and more effective as compared to the traditional products and procedures for treatment and other competing products.

ANSWER: The Summit Tapered Hip System is a safe, effective, reliable medical device. DePuy Defendants' marketing and promotional materials speak for themselves. DePuy Defendants deny any remaining allegations in Paragraph 204.

205. Mrs. Rouviere suffers from degenerative joint disease in her right hip.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 205.

206. On August 12, 2012, Plaintiff underwent a total right hip replacement at New York's Hospital for Special Surgery. Robert Buly, M.D., an orthopedic surgeon, performed the surgery. He implanted a "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System Stem into plaintiffs right hip.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 206.

207. Dr. Buly implanted the subject product in accordance with instructions, directions and other information made available by the Defendants, the manufacturers and designers.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 207.

208. Plaintiff followed all post-operative instructions from her physicians, but did not make improvements in her ability to walk, move her right leg, and regain range of motion.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 208.

209. Post-operatively, Ms. Rouviere's "MDM®X3®" ADM/MDM System, "The Restoration®"ADM/MDM System failed, by the beginning of 2013, she experienced pain and loss of range of motion.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 209. DePuy Defendants deny the allegations in paragraph 209 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 209.

210. Blood testing performed in May 2015 demonstrated highly elevated Chromium level of .9 MUG/L , Arsenic of MUG/L 5 and cobalt was not tested for at that time, and

in December 2016 , one month after the removal of the defective hip the Cobalt level was .6 MCG/L and chromium was < .2 MCG/L.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 210.

211. Mrs. Rouviere underwent revision surgery on November 11, 2016. The diagnosis given by Dr. Carlos Alvarado, MD was "*ASEPTIC INFLAMMATORY FAILURE, RIGHT HIP ARTHROPLASTY*."

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 211.

212. "Black metallic prosthetic particles" were ascertained by pathology studies of excised tissue as well with pathology reports of "Synovium and subsynovial connective tissue with pigment deposition, papillary hyperplasia, fibrosis and fibrin deposition."

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 212.

213. Plaintiffs "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System deteriorated, released and releases metals, including cobalt from its surface.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 213. DePuy Defendants deny the allegations in paragraph 213 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 213.

214. Plaintiffs "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System deteriorated, and released and releases cobalt from its interior.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 214. DePuy Defendants deny the allegations in paragraph 214 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 214.

215. Plaintiffs "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System deteriorated, and released and releases chromium from its surfaces.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 215. DePuy Defendants deny the allegations in paragraph 215 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 215.

216. Plaintiffs "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System deteriorated, and released and releases chromium from its interior.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 216. DePuy Defendants deny the allegations in paragraph 216 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 216.

217. Plaintiffs elevated blood levels of cobalt resulted directly from the deterioration of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 217. DePuy Defendants deny the allegations in paragraph 217 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 217.

218. Plaintiffs elevated blood levels of chromium resulted directly from the deterioration of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System stem.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 218. DePuy Defendants deny the allegations in paragraph 218 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 218.

219. The U.S. Department of Health and Human Services/Agency for Toxic Substances and Diseases Registry ("ATSDR") issues toxicological profiles for cobalt and chromium and other metals.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 219, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 219.

220. According to the ATSDR, absorption of excess cobalt results in effects to the respiratory, cardiovascular, gastrointestinal, hematological, hepatic, renal, endocrine, dermal, and ocular systems. Cardiomyopathy, damage to nerves, and dysfunctional blood clotting may result.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 220, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 220.

221. According to the ATSDR, absorption of excess chromium results in renal failure, hemolysis, liver damage, multiple organ failure and death.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 221, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 221.

222. Plaintiff does not suffer and has not suffered from occupational exposure to Titanium, Aluminum and other metals or hydroxyapatite and other coatings and textures.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 222.

223. Plaintiff does not suffer and has not suffered from occupational exposure to chromium and cobalt and other metals.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 223.

224. Plaintiff does not ingest and has not ingested, orally or through inhalation, Titanium, Aluminum and other metals or hydroxyapatite and other coatings and textures.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 224.

225. Plaintiff does not ingest and has not ingested, orally or through inhalation, chromium or colbalt and other metals.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 225.

226. Plaintiff has no source of exposure to Titanium, Aluminum and other metals or hydroxyapatite and other coatings and textures that would account for her elevated blood levels of Titanium, Aluminum and other metals or hydroxyapatite and other coatings and textures, other than the subject product.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 226.

227. Plaintiff has no source of exposure to chromium and cobalt and other metals that would account for her elevated blood levels of chromium or cobalt and other metals other than the subject product.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 227.

228. An appropriate, safe, competently and reasonably designed hip implant should not deteriorate prematurely and will not Titanium, Aluminum and other metals or hydroxyapatite and other coatings and textures into the human body.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 228, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 228.

229. An appropriate, safe, competently and reasonably designed hip implant should not deteriorate prematurely and will not release chromium and cobalt into the human body.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 229, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 229.

230. Unreasonably dangerous hip implants, as designed, will deteriorate prematurely and release Titanium, Aluminum and other metals or hydroxyapatite and other coatings and textures into the human body.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 230, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph

230 and expressly deny the Summit Tapered Hip System is unreasonably dangerous in any respect.

231. Unreasonably dangerous hip implants, as designed, will deteriorate prematurely and release chromium and cobalt and other metals into the human body.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 231, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 231 and expressly deny the Summit Tapered Hip System is unreasonably dangerous in any respect.

232. An appropriate, safe, competently and reasonably manufactured hip implant should not and will not deteriorate prematurely and release Titanium, Aluminum and other metals or hydroxyapatite and other coatings and textures into the human body.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 232, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 232.

233. An appropriate, safe, competently and reasonably manufactured hip implant should not and will not deteriorate prematurely and release chromium and cobalt and other metals into the human body.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 233, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the

DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 233.

234. Unreasonably dangerous hip implants, as manufactured, will deteriorate prematurely and release titanium, Titanium, Aluminum and other metals or hydroxyapatite and other coatings and textures into the human body.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 234, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 234 and expressly deny the Summit Tapered Hip System is unreasonably dangerous in any respect.

235. Unreasonably dangerous hip implants, as manufactured, will deteriorate prematurely and release chromium and cobalt and other metals into the human body.

ANSWER: DePuy Defendants make no response to rhetorical paragraph 235, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 235 and expressly deny the Summit Tapered Hip System is unreasonably dangerous in any respect.

236. The Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unreasonably dangerous in design in that it deteriorated prematurely and released and releases cobalt and other metals into the human body, including Plaintiff's body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 236. DePuy Defendants deny the allegations in paragraph 236 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 236.

237. The Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unreasonably dangerous in design in that it deteriorated prematurely and released and releases chromium into the human body, including Plaintiff's body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 237. DePuy Defendants deny the allegations in paragraph 237 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 237.

238. The Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unreasonably dangerous in manufacture in that it deteriorated prematurely and released and releases cobalt and other metals into the human body, including Plaintiffs body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 238. DePuy Defendants deny the allegations in paragraph 238 to the extent they are directed against DePuy Defendants. DePuy

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 238.

239. The Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unreasonably dangerous in manufacture in that it deteriorated prematurely and released and releases chromium into the human body, including Plaintiff's body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 239. DePuy Defendants deny the allegations in paragraph 239 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 239.

240. Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System deteriorated with usage under normal, ordinary and foreseeable conditions, resulting in the release of cobalt and chromium and other metals into the surrounding tissue, blood and organs of the recipient.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 240. DePuy Defendants deny the allegations in paragraph 240 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 240.

241. As manufacturers of hip replacement systems, the Defendants had the legal duty to warn physicians of the risk of deterioration of the "MDM X3 " ADM/MDM System, "The Restoration®" ADM/MDM System , the risk that the "MDM®X3®" ADM/MDM System, "The Restoration " ADM/MDM System composition, including chromium and cobalt and other metals, would deteriorate and corrode and release cobalt and chromium and other metals into the surrounding tissue, blood, and organs of the patient.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 241. DePuy Defendants deny the allegations in paragraph 241 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 241.

242. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no warning whatsoever that its usage under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and the release of cobalt and other metals from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 242. DePuy Defendants deny the allegations in paragraph 242 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 242.

243. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no warning whatsoever that its usage under normal, ordinary and foreseeable

conditions would result in corrosion and deterioration and the release of chromium from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 243. DePuy Defendants deny the allegations in paragraph 243 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 243.

244. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no warning whatsoever that its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and in elevated cobalt and other metals levels in the human body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 244. DePuy Defendants deny the allegations in paragraph 244 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 244.

245. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no warning whatsoever that its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and in elevated chromium levels in the human body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 245. DePuy Defendants deny the

allegations in paragraph 245 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 245.

246. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no written information that one of the adverse effects of usage under normal, ordinary and foreseeable conditions would be its deterioration and the release of cobalt and other metals from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 246. DePuy Defendants deny the allegations in paragraph 246 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 246.

247. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no written information that one of the adverse effects of usage under normal, ordinary and foreseeable conditions would be its deterioration and the release of chromium from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 247. DePuy Defendants deny the allegations in paragraph 247 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 247.

248. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no written information whatsoever that an adverse effect of its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would be corrosion and deterioration with resulting elevated cobalt and other metals levels in the human body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 248. DePuy Defendants deny the allegations in paragraph 248 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 248.

249. The "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System came with no written information whatsoever that an adverse effect of its usage, including the usage of its component parts, under normal, ordinary and foreseeable conditions would be would be corrosion and deterioration with elevated chromium levels in the human body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 249. DePuy Defendants deny the allegations in paragraph 249 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 249.

250. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System

and its component parts had they known that it usage under normal, ordinary and foreseeable conditions would result in would be corrosion and deterioration and the release of cobalt and other metals from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 250. DePuy Defendants deny the allegations in paragraph 250 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 250.

251. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and the release of chromium from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 251. DePuy Defendants deny the allegations in paragraph 251 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 251.

252. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had they known that its usage under normal, ordinary and

foreseeable conditions would result in corrosion and deterioration and elevated levels of cobalt and other metals in patients receiving the implant.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 252. DePuy Defendants deny the allegations in paragraph 252 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 252.

253. A reasonable healthcare provider, hospital, or implanting surgeon would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had they known that its usage under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and elevated levels of chromium in patients receiving the implant.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 253. DePuy Defendants deny the allegations in paragraph 253 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 253.

254. Defendants failed to advise Plaintiffs implanting surgeon that the usage of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System under normal, ordinary and foreseeable conditions would result in deterioration and the release of cobalt from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 254. DePuy Defendants deny the allegations in paragraph 254 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 254.

255. Defendants failed to advise Plaintiff s implanting surgeon that the usage of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System under normal, ordinary and foreseeable conditions would result in corrosion and deterioration and the release of chromium and other metals from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 255. DePuy Defendants deny the allegations in paragraph 255 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 255.

256. Defendants failed to advise Plaintiffs implanting surgeon that the usage of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System under normal, ordinary and foreseeable conditions would result in elevated cobalt and other metals levels in the human body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 256. DePuy Defendants deny the allegations in paragraph 256 to the extent they are directed against DePuy Defendants. DePuy

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 256.

257. Defendants failed to advise Plaintiffs implanting surgeon that the usage of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System under normal, ordinary and foreseeable conditions would result in elevated chromium levels in the human body.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 257. DePuy Defendants deny the allegations in paragraph 257 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 257.

258. Robert Buly, M.D. would not have selected "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System had he known that its usage under normal, ordinary and foreseeable conditions would result in the release of cobalt and other metals from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 258. DePuy Defendants deny the allegations in paragraph 258 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 258.

259. Robert Buly, M.D. would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in the release of chromium from its component parts.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 259. DePuy Defendants deny the allegations in paragraph 259 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 259.

260. Robert Buly, M.D. would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in corrosion and elevated levels of cobalt and other metals in patients receiving the implant, including Plaintiff.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 260. DePuy Defendants deny the allegations in paragraph 260 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 260.

261. Robert Buly, M.D. would not have selected the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its component parts had he known that its usage under normal, ordinary and foreseeable conditions would result in elevated

levels of chromium in patients receiving the implant, including the Plaintiff, Mrs. Rouviere.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 261. DePuy Defendants deny the allegations in paragraph 261 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 261.

262. Defendants did not have adequate and appropriate systems in place to collect and analyze any of the complaints they received from doctors, hospitals, and/or patients concerning the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System , as required by the FDA, thus leading to inconsistencies and irregularities in the way defendants kept track of complaints they received regarding the failure of the "MDM X3 " ADM/MDM System, "The Restoration®" ADM/MDM System.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 262. DePuy Defendants deny the allegations in paragraph 262 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 262.

263. Defendants knew, or should have known, of the seriousness of the risks of using "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System , based upon the state of knowledge of the "MDM®X3®" ADM/MDM System, "The

Restoration®" ADM/MDM System , as it existed at that time, and upon generally accepted medical and research standards and principles.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 263. DePuy Defendants deny the allegations in paragraph 263 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 263,

264. Defendants knew, or should have known, of the seriousness of the risks of using "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System based on the complaints they received from doctors, hospitals, and/or patients who used the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System demonstrating that the product was defective.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 264. DePuy Defendants deny the allegations in paragraph 264 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 264.

265. Defendants failed to send the necessary product failure reports to the FDA, as required by the FDA, indicating that the failure rate of "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was higher than the generally accepted standard rate of failure in the industry.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 265. DePuy Defendants deny the allegations in paragraph 265 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 265.

266. Defendants failed to appropriately and adequately warn the Plaintiff and her physicians, hospitals, and/or the FDA, of the serious and dangerous risks involved in using Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System including, but not limited to, severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 266. DePuy Defendants deny the allegations in paragraph 266 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 266.

267. Defendants misrepresented the known risks inherent in the use of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 267. DePuy Defendants deny the allegations in paragraph 267 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 267.

268. Defendants made certain claims which were distributed and circulated to the medical and healthcare professions that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were safe.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 268. DePuy Defendants deny the allegations in paragraph 268 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 268.

269. Defendants were careless and negligent in the manufacturing, testing, selling, distribution, merchandising, advertising, marketing, promotion, compounding, packaging, fabrication, warning, analyzing, marketing, and recommendation of "MDM X3 ®" ADM/MDM System, "The Restoration®" ADM/MDM System.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 269. DePuy Defendants deny the allegations in paragraph 269 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 269.

270. By reason of the foregoing, Plaintiff has suffered and/or is at an extremely high level of suffering serious and dangerous side effects, including but not limited to severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants deny the allegations in Paragraph 270.

271. Plaintiff has endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that she has and/or may suffer serious and dangerous side effects as a result of her "MDM® X3®" ADM/MDM System, "The Restoration®" ADM/MDM System. Plaintiff suffers from elevated blood metal levels and has had to undergo surgical explanation of her prosthetic hip and/or components. The plaintiff now lives without any right hip.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 271. DePuy Defendants deny the allegations in paragraph 271 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 271.

272. By reason of the foregoing, Plaintiff has been severely and permanently injured and/or has been exposed to risk of severe and permanent injury, and will require more constant and continuous medical monitoring and treatment than prior to her implantation of Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 272. DePuy Defendants deny the allegations in paragraph 272 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 272.

273. Moreover, "Medical devices in general, not just Class III devices, are subject to the FDA's current good manufacturing practice requirements (CGMP requirements). 21 U.S.C. § 360j(f); 21 C.F.R. § 820 et seq. These requirements set forth a quality control system and "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R § 820.1(a)(1). They are in place "to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." 21 C.F.R. § 820.1(a)(1). To comply with the CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. § 820.1-.250. By requiring manufacturers to adopt a variety of procedures and controls, "[t]he CGMP requirements ... leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. § 820.1-.250. By requiring manufacturers to adopt a variety of procedures and controls, "[t]he CGMP requirements ... leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective." *Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271, 279 (E.D.N.Y, 2009), *Gelber v. Stryker Corp.*, 788 F.Supp.2d 145, 152 (S.D.N.Y. 2011).

ANSWER: DePuy Defendants make no response to rhetorical paragraph 273, as it is purely explanatory in nature. To the extent Plaintiffs intended to make allegations against the

DePuy Defendants, DePuy Defendants deny any remaining allegations contained in paragraph 273.

274. In designing, developing, testing, manufacturing, assembling, packaging, promoting, labeling, marketing, distributing and selling the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System Defendants violated CGMP requirements for the reasons set forth above.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 274. DePuy Defendants deny the allegations in paragraph 274 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 274.

275. Defendants knowingly and deliberately made material misrepresentations to the FDA concerning the design, manufacture, safety, and efficacy of Defendants' "MDM® X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was a Section 510(k) medical device.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 275. DePuy Defendants deny the allegations in paragraph 275 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 275.

276. Defendants' claims to the FDA, that Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was substantially equivalent to predicate devices marketed prior to May 28, 1976, misled the FDA and the consuming public.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 276. DePuy Defendants deny the allegations in paragraph 276 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 276.

277. By marketing Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®"ADM/MDM System , as Section 510(k) medical device, Defendants were able to avoid conducting any formal review or undertaking any study of the products' safety or efficacy.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 277. DePuy Defendants deny the allegations in paragraph 277 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 277.

278. Defendants' "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was designed, patented, manufactured, labeled, marketed, and sold and distributed by Defendants, at all times relevant herein to the medical community and to patients as: safe, effective, reliable, medical devices; implanted by safe and effective,

minimally invasive surgical techniques for the treatment of patients undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of osteoarthritis and other conditions and/or diseases; and as safer and more effective as compared to the traditional products and procedures for treatment and other competing products.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 278. DePuy Defendants deny the allegations in paragraph 278 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 278.

FIRST CAUSE OF ACTION AS AGAINST THE DEFENDANTS DEPUY (NEGLIGENCE AND NEGLIGENCE *PER SE*)

279. Plaintiff repeats, reiterates and re alleges each and every allegation included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: DePuy Defendants incorporate their responses to paragraphs 1 through 278.

280. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, supplying, promoting, packaging, sale and/or distribution of the Summit Tapered Hip System and Stem into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

ANSWER: DePuy Defendants state that the allegations in Paragraph 280 regarding duty constitute conclusions of law to which no response is required. To the extent a response is required, and to the extent DePuy Defendants owed a duty, they satisfied that duty. DePuy Defendants deny the remaining allegations in Paragraph 280.

281. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the Summit Tapered Hip System and its stem into the interstate commerce in that Defendants knew or should have known that using the Summit Tapered Hip System and its stem created a high risk of unreasonable and dangerous side effects, including but not limited to severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants deny the allegations in Paragraph 281.

282. The negligence of the defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Designing and manufacturing the Summit Tapered Hip System and its stem without thoroughly nor clinically testing it;

(b) Not conducting sufficient testing programs to determine whether or not the aforesaid Summit Tapered Hip System and its stem was safe for use; in that defendants knew or should have known that the Summit Tapered Hip System and its stem was unsafe and unfit for use by reason of the dangers to recipients;

(c) Selling the Summit Tapered Hip System and its stem without making proper and sufficient tests to determine the dangers to recipients;

(d) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and/or the FDA of the dangers of the Summit Tapered Hip System and its stem, including but not limited to shedding, of titanium, aluminum, and other metals levels and exposure to hydroxyapatite, and other textures and coatings and corrosion in a recipients' body including the plaintiff.;

(e) Negligently failing to recall their dangerous and defective Summit Systems including the stem at the earliest date that it became known that said systems were, in fact, dangerous and defective;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and use the Summit Tapered Hip System and its stem;

(g) Failing to test the Summit Tapered Hip System and/or failing to adequately, sufficiently and properly test the Summit Tapered Hip System and its stem;

(h) Negligently advertising and recommending the use of the aforesaid Summit Tapered Hip System and its stem without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that the Summit Tapered Hip System and its stem were safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that the Summit Tapered Hip System and its stem had equivalent safety and efficacy as other, non-defective total hip replacement systems;

(k) Negligently designing the Summit Tapered Hip System and its stem in a manner which was dangerous to its recipients;

(l) Negligently manufacturing the Summit Tapered Hip System and its stem in a manner which was dangerous to its recipients;

(m) Negligently producing the Summit Tapered Hip System in a manner which was dangerous to its users;

(n) Negligently assembling the Summit Tapered Hip System and its stem in a manner which was dangerous to its recipients;

(o) Concealing information regarding tests, and/or reports, and/or studies from the Plaintiff and her physicians, demonstrating that the Summit Tapered Hip System was unsafe, dangerous, and/or non-conforming with accepted industry standards;

(p) Improperly concealing information from and/or misrepresenting information to the Plaintiffs, health care professionals, hospitals and/or the FDA, concerning the severity of risks and dangers of the Summit Tapered Hip System and its stem;

(q) Failing to properly warn and instruct regarding the increased frequency and severity of adverse events occurring with the Summit Tapered Hip System and its stem; and

(r) Failing to provide reasonable assurance with respect to the safety and effectiveness of the Summit Tapered Hip System and its stem.

ANSWER: DePuy Defendants deny the allegations in Paragraph 282, including its subparts.

283. Defendants violated statutes, rules and ordinates concerning the manufacturing, marketing, and/or testing of their product.

ANSWER: DePuy Defendants deny the allegations in Paragraph 283.

284. Defendants under-reported, underestimated and downplayed the serious dangers of the Summit Tapered Hip System and its stem.

ANSWER: DePuy Defendants deny the allegations in Paragraph 284.

285. Defendants were negligent in the designing, researching, supplying, manufacture, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Summit Tapered Hip System and its stem in that they:

(a) Failed to use due care in designing and manufacturing the Summit System so as to avoid the aforementioned risks to individuals when the Summit Tapered Hip System and its stem were used in total hip replacement surgeries;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse risks and side effects associated with the use of the Summit Tapered Hip System;

(c) Failed to accompany their product with proper warnings regarding all possible adverse risks and side effects concerning the failure and/or malfunction of the Summit Tapered Hip System and its stem;

(d) Failed to warn Plaintiff and her healthcare professionals, hospitals and/or the FDA of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects including but not limited to shedding of titanium, aluminum, and other metals levels and exposure to hydroxyapatite, and other textures and coatings and corrosion in a recipient's body including the plaintiff;

(e) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Summit Tapered Hip System and its stem;

(f) Failed to warn Plaintiff and her healthcare professionals, hospitals and/or the FDA prior to actively encouraging the sale of the Summit Tapered Hip System, either directly or

indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

(g) Were otherwise careless or negligent.

ANSWER: DePuy Defendants deny the allegations in Paragraph 282, including its subparts.

286. Defendants knew or should have known that consumers such as the Plaintiff would suffer foreseeable injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

ANSWER: DePuy Defendants deny the allegations in Paragraph 286.

287. Defendants' actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence *per se*.

ANSWER: DePuy Defendants deny the allegations in Paragraph 287.

288. Defendants' negligence was the proximate cause of Plaintiff s injuries, harm, and economic loss which she suffered and/or will continue to suffer.

ANSWER: DePuy Defendants deny the allegations in Paragraph 288.

289. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences. Plaintiff has suffered past and future loss of income.

ANSWER: DePuy Defendants deny the allegations in Paragraph 289

290. By reason of the foregoing, plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

ANSWER: DePuy Defendants deny the allegations in Paragraph 290.

SECOND CAUSE OF ACTION AS AGAINST THE DEPUY DEFENDANTS (STRICT PRODUCTS LIABILITY)

291. Plaintiff repeats, reiterates and re alleges each and every allegation included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: DePuy Defendants incorporate their responses to the preceding paragraphs herein.

292. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed the Summit Tapered Hip System as herein above described and Plaintiff was a recipient of said product.

ANSWER: DePuy Defendants admits that DePuy Orthopaedics, Inc. n/k/a Medical Device Business Services, Inc. designed, manufactured, tested, marketed, promoted, and sold the Summit Tapered Hip System.

293. The Summit Tapered Hip System was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without

substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

ANSWER: DePuy Defendants lack knowledge of information sufficient to form a belief as to the allegations in Paragraph 293 and therefore deny them.

294. At all relevant times, the Summit Tapered Hip System and its stem were in an unsafe, defective, and inherently dangerous condition, which was dangerous to recipients, and in particular, the Plaintiff herein.

ANSWER: DePuy Defendants deny the allegations in Paragraph 294.

295. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the Summit Tapered Hip System.

ANSWER: DePuy Defendants deny the allegations in Paragraph 295.

296. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective in design and/or formulation, in that, when it left the hands of the Defendant manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary healthcare provider would expect.

ANSWER: DePuy Defendants deny the allegations in Paragraph 296.

297. At all times herein mentioned, the Summit Tapered Hip System and its stem were in a defective condition and unsafe, and Defendants knew, or had reason to know, that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

ANSWER: DePuy Defendants deny the allegations in Paragraph 297.

298. Defendants knew, or should have known, that at all times herein mentioned, the Summit Tapered Hip System and its stem were in a defective condition, and was inherently dangerous and unsafe.

ANSWER: DePuy Defendants deny the allegations in Paragraph 298.

299. At the time of the Plaintiffs receipt and/or use of the Summit Tapered Hip System, the Summit System and stem was being used for the purposes and in a manner normally intended, namely as a total hip replacement system.

ANSWER: DePuy Defendants lack knowledge of information sufficient to form a belief as to the allegations in Paragraph 293 and therefore deny them.

300. Defendants, with this knowledge, voluntarily designed the Summit Tapered Hip System and its stem in a dangerous condition for use by the public, and in particular the plaintiff and/or her health care professionals.

ANSWER: DePuy Defendants deny the allegations in Paragraph 300.

301. Defendants had a duty to create a product that was not unreasonably dangerous or its normal, intended use.

ANSWER: DePuy Defendants state that the allegations in Paragraph 301 regarding duty constitute conclusions of law to which no response is required. To the extent a response is required, and to the extent Defendants owed a duty, they satisfied that duty. DePuy Defendants deny the allegations in Paragraph 301.

302. Defendants created a product unreasonably dangerous for its normal, intended use.

ANSWER: DePuy Defendants deny the allegations in Paragraph 302.

303. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was manufactured defectively in that said Summit Tapered Hip System left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

ANSWER: DePuy Defendants deny the allegations in Paragraph 303.

304. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Summit Tapered Hip System and stem was manufactured.

ANSWER: DePuy Defendants deny the allegations in Paragraph 304.

305. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to

the health of consumers and to the Plaintiff in particular, and defendants are therefore strictly liable for the injuries sustained by the plaintiff.

ANSWER: DePuy Defendants deny the allegations in Paragraph 305.

306. The Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

ANSWER: DePuy Defendants lack knowledge of information sufficient to form a belief as to the allegations in Paragraph 293 and therefore deny them.

307. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective due to inadequate warnings or instructions because the manufacturer knew or should have known that the product created a risk of unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery, as well as other severe and permanent health consequences, and the Defendants failed to adequately warn of said risk.

ANSWER: DePuy Defendants deny the allegations in Paragraph 307.

308. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective due to inadequate warnings and/or inadequate testing.

ANSWER: DePuy Defendants deny the allegations in Paragraph 308.

309. The Summit Tapered Hip System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post marketing surveillance and/or warnings because, after the manufacturer knew or should have known of the unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery, as well as other severe and permanent health consequences, and defendants failed to provide adequate warnings to users or consumers of the product, and continued to promote the product.

ANSWER: DePuy Defendants deny the allegations in Paragraph 309.

310. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, the Summit Tapered Hip System and its stem.

ANSWER: DePuy Defendants deny the allegations in Paragraph 310.

311. Defendants' defective design, manufacturing defect, and inadequate warnings of the Summit Tapered Hip System and its stem were acts that amount to willful, wanton, and/or reckless conduct by defendants.

ANSWER: DePuy Defendants deny the allegations in Paragraph 311.

312. That said defects in Defendants' Summit Tapered Hip System and it stem were substantial factors in causing plaintiff s injuries.

ANSWER: DePuy Defendants deny the allegations in Paragraph 312.

313. Asa result of the foregoing acts and omissions, Plaintiff was and/or still is caused to suffer and/or is at a greater increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants deny the allegations in Paragraph 313.

314. Asa result of the foregoing acts and omissions, the Plaintiff, Mrs. Rouviere requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services. Plaintiff has suffered past and future loss of income.

ANSWER: DePuy Defendants deny the allegations in Paragraph 314.

315. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

ANSWER: DePuy Defendants deny the allegations in Paragraph 315.

THIRD CAUSE OF ACTION AS AGAINST THE DEPUY DEFENDANTS (BREACH OF EXPRESS WARRANTY)

316. Plaintiff repeats, reiterates and re alleges each and every allegation included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: DePuy Defendants incorporate their responses to the preceding paragraphs herein.

317. Defendants expressly warranted that the Summit Tapered Hip System and stem were safe and/or well accepted by users.

ANSWER: DePuy Defendants deny the allegations in Paragraph 317.

318. The Summit Tapered Hip System and stem does not conform to these express representations because the Summit Tapered Hip System and stem is not safe and has numerous serious risks and side effects. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

ANSWER: DePuy Defendants deny the allegations in Paragraph 318.

319. Plaintiff did rely on the express warranties of the Defendants herein.

ANSWER: DePuy Defendants deny the allegations in Paragraph 319.

320. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the defendants for use of the Summit Tapered Hip System and stem in total hip replacement surgeries.

ANSWER: DePuy Defendants deny the allegations in Paragraph 320.

321. Defendants herein breached the aforesaid express warranties, as their Summit Systems and stem were defective.

ANSWER: DePuy Defendants deny the allegations in Paragraph 321.

322. Defendants expressly represented to the users, their physicians, healthcare providers, and/or the FDA that the Summit Tapered Hip System and stem were safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

ANSWER: Paragraph 322 contains legal conclusions to which no response is necessary. To the extent a response is required, DePuy Defendants state that the Summit Tapered Hip System is safe and fit for its intended purpose and deny that it is unreasonably dangerous. DePuy Defendants deny any remaining allegations in Paragraph 322.

323. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Summit Tapered Hip System and stem was not safe and fit for the use intended, and, in fact, produced serious injuries lo the users.

ANSWER: DePuy Defendants deny the allegations in Paragraph 323.

324. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at an greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants deny the allegations in Paragraph 324.

325. Asa result of the foregoing acts and omissions, the Plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services. Plaintiff has suffered past and future loss of income.

ANSWER: DePuy Defendants deny the allegations in Paragraph 325.

326. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction; over this action.

ANSWER: DePuy Defendants deny the allegations in Paragraph 326.

FOURTH CAUSE OF ACTION AS AGAINST THE DEPUY DEFENDANTS (BREACH OF IMPLIED WARRANTIES)

327. Plaintiff repeats, reiterates and re alleges each and every allegation included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: DePuy Defendants incorporate their responses to the preceding paragraphs herein.

328. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted and sold the Summit System and stem, which is used in total hip replacement surgeries. At the time defendants marketed, sold, and distributed the Summit Tapered Hip System for use by

Plaintiff, Defendants knew of the use for which the Summit Tapered Hip System and stem was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

ANSWER: DePuy Defendants deny the allegations in Paragraph 328.

329. Defendants impliedly represented and wan-anted to the users and their physicians, healthcare providers, and/or the FDA that the Summit Tapered Hip System and stem was safe and of merchantable quality, and fit for the ordinary purpose for which said product was to be used.

ANSWER:

330. That said representations and warranties aforementioned were false, misleading and inaccurate in that the Summit Tapered Hip System and stem was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

ANSWER: DePuy Defendants deny the allegations in Paragraph 330.

331. Plaintiff, and members of the medical community, did rely on said implied warranties of merchantability and/or fitness for a particular use and purpose.

ANSWER: DePuy Defendants deny the allegations in Paragraph 331.

332. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of defendants as to whether the Summit Tapered Hip System and stem was of merchantable quality and safe and fit for its intended use.

ANSWER: DePuy Defendants deny the allegations in Paragraph 332.

333. The Summit Tapered Hip System stem was injected into the stream of commerce by the defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

ANSWER: DePuy Defendants deny the allegations in Paragraph 333.

334. Defendants herein breached the aforesaid implied warranties, as their Summit System was not fit for its intended purposes and uses.

ANSWER: DePuy Defendants deny the allegations in Paragraph 334.

335. Asa result of the foregoing acts and omissions, Plaintiff was, and/or still is, caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants deny the allegations in Paragraph 335.

336. As a result of the foregoing acts and omissions, plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services. Plaintiff has suffered past and future loss of income.

ANSWER: DePuy Defendants deny the allegations in Paragraph 336.

337. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

ANSWER: DePuy Defendants deny the allegations in Paragraph 337.

FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS STRYKER (NEGLIGENCE AND NEGLIGENCE *PER SE*)

338. Plaintiff repeats, reiterates and re alleges each and every allegation included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: DePuy Defendants incorporate their responses to the preceding paragraphs herein.

339. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, supplying, promoting, packaging, sale and/or distribution of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 339. DePuy Defendants deny the allegations in paragraph 339 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 339.

340. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System into the interstate commerce in that Defendants knew or should have known that using the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System created a high risk of unreasonable and dangerous side effects, including but not limited to severe pain and suffering, the need for additional surgery, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 340. DePuy Defendants deny the allegations in paragraph 340 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 340.

341. The negligence of the defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Designing and manufacturing the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System without thoroughly testing it;

(b) Not conducting sufficient testing programs to determine whether or not the aforesaid "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was safe for use; in that defendants knew or should have known that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unsafe and unfit for use by reason of the dangers to recipients;

(c) Selling the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System without making proper and sufficient tests to determine the dangers to recipients;

(d) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and/or the FDA of the dangers of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System;

(e) Negligently failing to recall their dangerous and defective "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System at the earliest date that it became known that said systems were, in fact, dangerous and defective;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and use the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System;

(g) Failing to test the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and/or failing to adequately, sufficiently and properly test the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System;

(h) Negligently advertising and recommending the use of the aforesaid "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System had equivalent safety and efficacy as other, non-defective total hip replacement systems;

(k) Negligently designing the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in a manner which was dangerous to its recipients;

(l) Negligently manufacturing the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in a manner which was dangerous to its recipients;

(m) Negligently producing the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in a manner which was dangerous to its users;

(n) Negligently assembling the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and its stem in a manner which was dangerous to its recipients;

(o) Concealing information regarding tests, and/or reports, and/or studies from the Plaintiff and her physicians, demonstrating that the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unsafe, dangerous, and/or non-conforming with accepted industry standards;

(p) Improperly concealing information from and/or misrepresenting information to the Plaintiffs, health care professionals, hospitals and/or the FDA, concerning the severity of risks and dangers of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System;

(q) Failing to properly warn and instruct regarding the increased frequency and severity of adverse events occurring with the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System; and

(r) Failing to provide reasonable assurance with respect to the safety and effectiveness of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 341. DePuy Defendants deny the allegations in paragraph 341 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 341.

342. Defendants violated statutes, rules and ordinates concerning the manufacturing, marketing, and/or testing of their product.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 342. DePuy Defendants deny the allegations in paragraph 342 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 342.

343. Defendants under-reported, underestimated and downplayed the serious dangers of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 343. DePuy Defendants deny the allegations in paragraph 343 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 343.

344. Defendants were negligent in the designing, researching, supplying, manufacture, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in that they:

(a) Failed to use due care in designing and manufacturing the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System so as to avoid the aforementioned risks to individuals when the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were used in total hip replacement surgeries;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse risks and side effects associated with the use of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System;

(c) Failed to accompany their product with proper warnings regarding all possible adverse risks and side effects concerning the failure and/or malfunction of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System;

(d) Failed to warn Plaintiff and her healthcare professionals, hospitals and/or the FDA of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(e) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System;

(f) Failed to warn Plaintiff and her healthcare professionals, hospitals and/or the FDA prior to actively encouraging the sale of the "MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System, either directly or indirectly, orally or in writing, about the

need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

(g) Were otherwise careless or negligent.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 344. DePuy Defendants deny the allegations in paragraph 344 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 344.

345. Defendants knew or should have known that consumers such as the Plaintiff would suffer foreseeable injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 345. DePuy Defendants deny the allegations in paragraph 345 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 345.

346. Defendants' actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence *per se*.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 346. DePuy Defendants deny the allegations in paragraph 346 to the extent they are directed against DePuy Defendants. DePuy

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 346.

347. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm, and economic loss which she suffered and/or will continue to suffer. Plaintiff has suffered past and future loss of income.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 347. DePuy Defendants deny the allegations in paragraph 347 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 347.

348. As a result of the foregoing acts and omissions, the Plaintiff was and/or still has ~~caused to~~ [sic] suffered and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 348. DePuy Defendants deny the allegations in paragraph 348 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 348.

349. By reason of the foregoing, plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 349. DePuy Defendants deny the allegations in paragraph 349 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 349.

SIXTH CAUSE OF ACTION AS AGAINST THE STRYKER DEFENDANTS (STRICT PRODUCTS LIABILITY)

350. Plaintiff repeats, reiterates and re alleges each and every allegation included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: DePuy Defendants incorporate their responses to the preceding paragraphs herein.

351. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed MDM®X3®"ADM/MDM System, "The Restoration®" ADM/MDM System as hereinabove described and Plaintiff was a recipient of said product.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 351. DePuy Defendants deny the allegations in paragraph 351 to the extent they are directed against DePuy Defendants. DePuy

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 351.

352. MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 352. DePuy Defendants deny the allegations in paragraph 352 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 352.

353. At all relevant times, MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were in an unsafe, defective, and inherently dangerous condition, which was dangerous to recipients, and in particular, the Plaintiff herein.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 353. DePuy Defendants deny the allegations in paragraph 353 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 353.

354. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and

distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 354. DePuy Defendants deny the allegations in paragraph 354 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 354.

355. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective in design and/or formulation, in that, when it left the hands of the Defendant manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary healthcare provider would expect.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 355. DePuy Defendants deny the allegations in paragraph 355 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 355.

356. Defendants knew, or should have known, that at all times herein mentioned, the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were in a defective condition, and was inherently dangerous and unsafe.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 356. DePuy Defendants deny the allegations in paragraph 356 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 356

357. At the time of the Plaintiffs receipt and/or use of the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was being used for the purposes and in a manner normally intended, namely as a total hip replacement system.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 357. DePuy Defendants deny the allegations in paragraph 357 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 357.

358. Defendants, with this knowledge, voluntarily designed the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in a dangerous condition for use by the public, and in particular the plaintiff and/or her health care professionals.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 358. DePuy Defendants deny the allegations in paragraph 358 to the extent they are directed against DePuy Defendants. DePuy

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 358.

359. Defendants had a duty to create a product that was not unreasonably dangerous or its normal, intended use.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 359. DePuy Defendants deny the allegations in paragraph 359 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 359.

360. Defendants created a product unreasonably dangerous for its normal, intended use.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 360. DePuy Defendants deny the allegations in paragraph 360 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 360.

361. MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was manufactured defectively in that said MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System left the hands of

Defendants in a defective condition and was unreasonably dangerous to its intended users.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 361. DePuy Defendants deny the allegations in paragraph 361 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 361.

362. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and stem was manufactured.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 362. DePuy Defendants deny the allegations in paragraph 362 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 362.

363. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and defendants are therefore strictly liable for the injuries sustained by the plaintiff.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 363. DePuy Defendants deny the allegations in paragraph 363 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 363.

364. The Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 364. DePuy Defendants deny the allegations in paragraph 364 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 364.

365. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective due to inadequate warnings or instructions because the manufacturer knew or should have known that the product created a risk of unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery, as well as other severe and permanent health consequences, and the Defendants failed to adequately warn of said risk.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 365. DePuy Defendants deny the allegations in paragraph 365 to the extent they are directed against DePuy Defendants. DePuy

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 365.

366. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by defendants was defective due to inadequate warnings and/or inadequate testing.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 366. DePuy Defendants deny the allegations in paragraph 366 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 366.

367. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post marketing surveillance and/or warnings because, after the manufacturer knew or should have known of the unreasonable, dangerous side effects, including but not limited to severe pain and suffering, and the need for additional surgery, as well as other severe and permanent health consequences, and defendants failed to provide adequate warnings to users or consumers of the product, and continued to promote the product.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 367. DePuy Defendants deny the allegations in paragraph 367 to the extent they are directed against DePuy Defendants. DePuy

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 367.

368. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 368. DePuy Defendants deny the allegations in paragraph 368 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 368.

369. Defendants' defective design, manufacturing defect, and inadequate warnings of the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were acts that amount to willful, wanton, and/or reckless conduct by defendants.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 369. DePuy Defendants deny the allegations in paragraph 369 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 369.

370. That said defects in Defendants' MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were substantial factors in causing plaintiffs injuries.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 370. DePuy Defendants deny the allegations in paragraph 370 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 370.

371. As a result of the foregoing acts and omissions, Plaintiff was and/or still is caused to suffer and/or is at a greater increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 371. DePuy Defendants deny the allegations in paragraph 371 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 371.

372. As a result of the foregoing acts and omissions, the Plaintiff, Mrs. Rouviere requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services. Plaintiff has suffered past and future loss of income.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 372. DePuy Defendants deny the

allegations in paragraph 372 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 372.

373. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 373. DePuy Defendants deny the allegations in paragraph 373 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 373.

SEVENTH CAUSE OF ACTION AS AGAINST THE STRYKER DEFENDANTS (BREACH OF EXPRESS WARRANTY)

374. Plaintiff repeats, reiterates and re alleges each and every allegation included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: DePuy Defendants incorporate their responses to the preceding paragraphs herein.

375. Defendants expressly warranted that the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and stem were safe and/or well accepted by users.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 375. DePuy Defendants deny the allegations in paragraph 375 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 375.

376. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System does not conform to these express representations because the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System and stem is not safe and has numerous serious risks and side effects. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 376. DePuy Defendants deny the allegations in paragraph 376 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 376.

377. Plaintiff did rely on the express warranties of the Defendants herein.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 377. DePuy Defendants deny the allegations in paragraph 377 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 377.

378. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the defendants for use of the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System in total hip replacement surgeries.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 378. DePuy Defendants deny the allegations in paragraph 378 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 378.

379. Defendants herein breached the aforesaid express warranties, as their MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were defective.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 379. DePuy Defendants deny the allegations in paragraph 379 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 379.

380. Defendants expressly represented to the users, their physicians, healthcare providers, and/or the FDA that the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System were safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 380. DePuy Defendants deny the allegations in paragraph 380 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 380.

381. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was not safe and fit for the use intended, and, in fact, produced serious injuries to the users.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 381. DePuy Defendants deny the allegations in paragraph 381 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 381.

382. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 382. DePuy Defendants deny the allegations in paragraph 382 to the extent they are directed against DePuy Defendants. DePuy

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 382.

383. As a result of the foregoing acts and omissions, the Plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services. Plaintiff has suffered past and future loss of income.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 383. DePuy Defendants deny the allegations in paragraph 383 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 383.

384. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction; over this action.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 384. DePuy Defendants deny the allegations in paragraph 384 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 384.

EIGHTH CAUSE OF ACTION AS AGAINST THE STRYKER DEFENDANTS (BREACH OF IMPLIED WARRANTIES)

385. Plaintiff repeats, reiterates and re alleges each and every allegation included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

ANSWER: DePuy Defendants incorporate their responses to the preceding paragraphs herein.

386. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted and sold the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System, which is used in total hip replacement surgeries. At the time defendants marketed, sold, and distributed MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System for use by Plaintiff, Defendants knew of the use for which the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 386. DePuy Defendants deny the allegations in paragraph 386 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 386.

387. Defendants impliedly represented and wan-anted to the users and their physicians, healthcare providers, and/or the FDA that MDM®X3®" ADM/MDM System, "The

Restoration®" ADM/MDM System was safe and of merchantable quality, and fit for the ordinary purpose for which said product was to be used.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 387. DePuy Defendants deny the allegations in paragraph 387 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 387.

388. That said representations and warranties aforementioned were false, misleading and inaccurate in that MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was unsafe, unreasonably dangerous, improper, not of merchantable quality and defective.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 388. DePuy Defendants deny the allegations in paragraph 388 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 388.

389. Plaintiff, and members of the medical community, did rely on said implied warranties of merchantability and/or fitness for a particular use and purpose.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 389. DePuy Defendants deny the allegations in paragraph 389 to the extent they are directed against DePuy Defendants. DePuy

Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 389.

390. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of defendants as to whether the MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was of merchantable quality and safe and fit for its intended use.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 390. DePuy Defendants deny the allegations in paragraph 390 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 390.

391. The MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was injected into the stream of commerce by the defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 391. DePuy Defendants deny the allegations in paragraph 391 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 391.

392. Defendants herein breached the aforesaid implied warranties, as their MDM®X3®" ADM/MDM System, "The Restoration®" ADM/MDM System was not fit for its intended purposes and uses.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 392. DePuy Defendants deny the allegations in paragraph 392 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 392.

393. Asa result of the foregoing acts and omissions, Plaintiff was, and/or still is, caused to suffer and/or is at a greatly increased risk of suffering serious, dangerous side effects, including, but not limited to, severe pain and suffering, revision surgery and the strong possibility of additional surgeries, as well as other severe and permanent health consequences.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 393. DePuy Defendants deny the allegations in paragraph 393 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 393.

394. As a result of the foregoing acts and omissions, plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be

required to obtain further medical and/or hospital care, attention, and services. Plaintiff has suffered past and future loss of income.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 394. DePuy Defendants deny the allegations in paragraph 394 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 394.

395. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this action.

ANSWER: DePuy Defendants do not understand Plaintiffs to be asserting any allegations against the DePuy Defendants in Paragraph 395. DePuy Defendants deny the allegations in paragraph 395 to the extent they are directed against DePuy Defendants. DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 395.

NINTH CAUSE OF ACTION AS AGAINST THE STRYKER & DEPUY – HUSBAND ANDRE ROUVIER'S CLAIM FOR LOSS OF CONSORTIUM

396. Plaintiff repeats, reiterates and re alleges each and every allegation included in paragraphs 1 and 278 of this Complaint contained in each of the foregoing paragraphs inclusive, and specifically re alleges and re adopts all previous eight causes of action with the same force and effect as if more fully set forth herein.

ANSWER: DePuy Defendants incorporate their responses to the preceding paragraphs herein.

397. At the time of the acts as plead in this the Plaintiffs' Complaint, the Plaintiffs were married and that the Plaintiffs continue to be married.

ANSWER: DePuy Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 397.

398. That as a result of the wrongful and negligent, and deliberate acts of the Defendants, and each of them, the Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their marital relationship.

ANSWER: DePuy Defendants deny the allegations in paragraph 398.

399. That all the injuries and damages were caused solely and proximately by the negligence of the Depuy and Stryker Defendants

ANSWER: DePuy Defendants deny the allegations in paragraph 399.

SEPARATE DEFENSES

DePuy Defendants also assert the following separate defenses. By alleging the separate defenses set forth below, DePuy Defendants are not in any way agreeing or conceding that they have the burden of proof or the burden of persuasion on any of these issues.

FIRST SEPARATE DEFENSE

Plaintiffs' Amended Complaint fails, in whole or in part, to state a claim upon which relief may be granted.

SECOND SEPARATE DEFENSE

The injuries and damages claimed by Plaintiffs, if any, were caused in whole or in part by the acts or omissions of persons over whom DePuy Defendants have no control or right of control, including but not limited to the other defendants named in this lawsuit.

THIRD SEPARATE DEFENSE

Plaintiffs are barred from recovery to the extent that they were negligent, careless, and at fault and conducted themselves so as to contribute substantially to their alleged injuries and damages.

FOURTH SEPARATE DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the products at issue in this case, and such assumption of the risks bars in whole or in part the damages Plaintiffs seek to recover herein.

FIFTH SEPARATE DEFENSE

Plaintiffs' alleged damages, if any, are barred in whole or in part by Plaintiffs' failure to mitigate such damages.

SIXTH SEPARATE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the product at issue was at all relevant times manufactured and sold consistent with available technology, scientific knowledge, and the state of the art, and in compliance with all federal, state, and local laws and regulations, and was accompanied by product information and warnings that were reasonable, full and

adequate and in accordance with FDA regulating requirements and the state of medical and scientific knowledge then in existence.

SEVENTH SEPARATE DEFENSE

If DePuy Defendants' products are unsafe in any way, they are unavoidably unsafe. Plaintiffs' purported action is, therefore, barred by Comment k of § 402A of the Restatement (Second) of Torts and/or other applicable law.

EIGHTH SEPARATE DEFENSE

Any alleged conduct or actions of the DePuy Defendants was not the proximate or producing cause of Plaintiffs' alleged injuries or damages.

NINTH SEPARATE DEFENSE

Plaintiffs' alleged injuries and damages attributable to the use of the products at issue in this case, if any, were not legally caused by the products at issue, but instead were legally caused by intervening and superseding causes or circumstances.

TENTH SEPARATE DEFENSE

If Plaintiffs incurred any injuries or damages as a result of the use of the products at issue, which DePuy Defendants deny, such injuries or damages were due to an idiosyncratic or idiopathic reaction, or by an unforeseeable or pre-existing condition.

ELEVENTH SEPARATE DEFENSE

Plaintiffs' claims and causes of action are preempted by Medical Device Amendments to the Federal Food, Drug & Cosmetic Act and the FDA regulations promulgated pursuant thereto.

TWELFTH SEPARATE DEFENSE

Plaintiffs' causes of action are barred by the applicable statutes of limitation, statutes of repose, and/or doctrine of laches.

THIRTEENTH SEPARATE DEFENSE

Plaintiffs' causes of action are barred by the doctrines of informed consent, release, and waiver.

FOURTEENTH SEPARATE DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine and/or the sophisticated user doctrine.

FIFTEENTH SEPARATE DEFENSE

DePuy Defendants did not make to Plaintiffs nor did it breach any express or implied warranties and/or breach of any warranties created by law. To the extent that Plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity with Defendant and/or failure of Plaintiffs, or Plaintiffs' representatives, to give timely notice to the DePuy Defendants of any alleged breach of warranty. DePuy Defendants further specifically plead as to any breach of warranty claim all defenses under the Uniform Commercial Code existing and which may arise in the future as enacted in the State of New York or any other state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

SIXTEENTH SEPARATE DEFENSE

Plaintiffs' claims of product defects are barred by Sections 2, 4, and 6(c) and (d) of the Restatement (Third) of Torts: Products Liability.

SEVENTEENTH SEPARATE DEFENSE

Plaintiffs' claims should be diminished in whole or in part in the amount paid to Plaintiffs by any party or non-party with whom Plaintiffs have settled or may settle.

EIGHTEENTH SEPARATE DEFENSE

Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

NINETEENTH SEPARATE DEFENSE

DePuy Defendants are entitled to, and claim the benefits of, all defenses and presumptions set forth in or arising from any rule of law or statute in any state whose law is deemed to apply in this case.

TWENTIETH SEPARATE DEFENSE

Plaintiffs' claims are barred by the equitable doctrine of estoppel.

TWENTY-FIRST SEPARATE DEFENSE

Plaintiffs' alleged injuries are a result of pre-existing and/or unrelated medical conditions for which DePuy Defendants are not responsible.

TWENTY-SECOND SEPARATE DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

TWENTY-THIRD SEPARATE DEFENSE

Plaintiffs have failed to plead allegations of fraud, mistake, or deception with the specificity or detail required.

TWENTY-FOURTH SEPARATE DEFENSE

To the extent that the products at issue in this lawsuit were changed, altered, or modified after they left the control of the manufacturer, such change, alteration, or modification was the legal cause of Plaintiffs' injuries and damages, if any.

TWENTY-FIFTH SEPARATE DEFENSE

Plaintiffs' product liability claims are barred because the benefits of the relevant products outweighed the risk.

TWENTY-SIXTH SEPARATE DEFENSE

Any claim for punitive or exemplary damages against DePuy Defendants are unconstitutional in that recovery of punitive or exemplary damages in this case would violate Defendant's constitutional rights to due process and equal protection under the Fourteenth Amendment to the Constitution of the United States and similar protections afforded by the New York and Indiana state constitutions, and any other state whose law is deemed to apply in this case, and that any law of the state of New York, whether enacted by the state's legislature or founded upon a decision or decisions of the courts, or that of any other state whose law is deemed to apply in this case, that would permit recovery of punitive or exemplary damages, is unconstitutional under these provisions.

TWENTY-SEVENTH SEPARATE DEFENSE

Any claim for punitive or exemplary damages against Defendant is unconstitutional in that the standards for granting and asserting punitive or exemplary damages do not prohibit other plaintiffs from seeking and recovering such damages against DePuy Defendants for the same allegations of defect in the same products, and as such constitute multiple punishments for the same alleged conduct resulting in deprivation of DePuy Defendant's property without due process of law and will result in unjustified windfalls for Plaintiffs and Plaintiffs' counsel, in violation of the Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States and similar protections afforded by the New York and Indiana state constitutions, and that of any other state whose law is deemed to apply in this case.

TWENTY-EIGHTH SEPARATE DEFENSE

Any claim for punitive damages against DePuy Defendants cannot be maintained because an award of punitive damages under current New York law, and any other state's law deemed to apply to this action, would be void for vagueness, both facially and as applied. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fifth and Fourteenth Amendments to the United States Constitution, the due process provisions of the New York state constitution, and the common law and public policies of New York and similar protections afforded by any other state whose law is deemed to apply in this case.

TWENTY-NINTH SEPARATE DEFENSE

To the extent that the law of New York and any other state whose law is deemed to apply in this case, permit punishment to be measured by the net worth or financial status of Defendant and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious, and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, allows punishment to be imposed based on lawful profits and conduct of DePuy Defendants in other states, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the

Commerce Clause of the United States Constitution, the state laws and constitutional provisions of New York and similar protections afforded by any other state whose law is deemed to apply in this case.

THIRTIETH SEPARATE DEFENSE

The product at issue was in compliance with all applicable codes, standards, regulations and specifications established by the United States and/or the State of New York, or by any agencies of the United States and/or the State of New York, and accordingly the product at issue is presumed to be non-defective.

THIRTY-FIRST SEPARATE DEFENSE

ANSWER: This Court does not have personal jurisdiction over Johnson & Johnson, Johnson & Johnson Services, Inc., or DePuy International Limited.

THIRTY-SECOND SEPARATE DEFENSE

DePuy Defendants hereby raise, assert, and preserve its defense of improper venue or *forum non conveniens*.

THIRTY-THIRD SEPARATE DEFENSE

DePuy Defendants assert the limitations of prejudgment interest set forth by New York common law to the extent that New York law applies to this matter.

THIRTY-FOURTH SEPARATE DEFENSE

DePuy Defendants are entitled to the protections and limitations afforded under New York law.

THIRTY-FIFTH SEPARATE DEFENSE

To the extent that New York law applies in this matter, if DePuy Defendants are found liable to Plaintiff for any non-economic loss allegedly suffered by Plaintiff, which is denied, such

liability equals fifty percent or less of the total liability of all persons liable, and the aggregate liability of such other persons equals or exceeds fifty percent of the total liability. Therefore, pursuant to New York CPLR Article 16, DePuy Defendants' liability, if any, to Plaintiff for non-economic loss shall not exceed Defendants' equitable share determined in accordance with the relative culpability of each person causing or contributing to the total liability for such non-economic loss.

THIRTY-SIXTH SEPARATE DEFENSE

To the extent Plaintiff has or will settle with any person with respect to the allegations in the Second Amended Complaint, the liability of Defendant, if any, shall be reduced pursuant to §15-108 of the General Obligations Law.

THIRTY-SEVENTH SEPARATE DEFENSE

DePuy Defendants asserts all defenses available under the New York Consumer Protection Act, codified in New York General Business Law §§349-350.

THIRTY-EIGHTH SEPARATE DEFENSE

Plaintiff is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design that would have prevented the harm alleged by Plaintiff without substantially impairing the usefulness or intended purpose of the product.

THIRTY-NINETH SEPARATE DEFENSE

To the extent that New York law applies in this matter, if Defendant is found liable to Plaintiff for any economic loss allegedly suffered by Plaintiff, which is denied, all of Plaintiff's alleged economic loss was, or with reasonable certainty will be, replaced or indemnified in whole or in part from collateral sources. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Second Amended Complaint, such benefits are not recoverable in this action under New York

law. To the extent Defendant may be found liable to Plaintiff, which liability is expressly denied, Defendant would be entitled to a set off for the total of all amounts paid to Plaintiff by other sources.

FORTIETH SEPARATE DEFENSE

Defendant is entitled to the protections and limitations afforded under Ind. Code Ann. §§ 34-51-3-1, *et seq*.

FORTY-FIRST SEPARATE DEFENSE

Defendant reserves the right to raise such further and additional defenses as may be available upon the facts to be developed in discovery and under other applicable substantive law.

PRAYER

WHEREFORE, DePuy Defendants respectfully pray as follows:

1. That Plaintiffs take nothing by reason of the Amended Complaint;

2. That the Amended Complaint against DePuy Defendants be dismissed in its entirety;

3. That DePuy Defendants recover its reasonable costs of suit incurred in defense of this action; and

4. For such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

DePuy Defendants demand trial by jury on all issues so triable.

/s/ Joseph G. Eaton
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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was electronically served on the following counsel of record via first class United States mail and the Court's electronic filing system on this 7th day of December:

Andre Rouviere
Jodi Rouviere
4070 Laguna Street
Coral Gables, Florida 33146

/s/ Joseph G. Eaton

DMS 13553600v1